EXHIBIT 3

WILLIAM J. VIGILANTE, JR.

IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TENNESSEE WESTERN DIVISION

- - -

GARY BRYAN BRACKIN, individually and in his capacity as Surviving Spouse of PAMELA W. BRACKIN, Deceased,
Plaintiff,

vs.

MEDTRONIC, INC., et al.,
Defendants. : No. 2:17-cv-2101

- - -

September 14, 2018

- - -

Videotape deposition of WILLIAM J. VIGILANTE, JR. taken pursuant to notice held at the Law Offices of Williams Cedar, LLC, 1515 Market Street, Suite 1300, Philadelphia, Pennsylvania 19102, commencing at 10:07 a.m., on the above date, before Jennifer P. Miller, RPR, CCR, CRR #30XI00235100 and Notary Public.

Job Number: 147847

WILLIAM J. VIGILANTE, JR.

A P P E A R A N C E S:

KEVIN HAVERTY, ESQUIRE
WILLIAMS CEDAR
8 Kings Highway West
Haddonfield, NJ 08033
Counsel for Plaintiff

CLIFF MERRELL, ESQUIRE
GREENBERG TRAURIG
Terminus 200
333 Piedmont Road, NE
Atlanta, GA 30305
Counsel for Defendants

ALSO PRESENT: Dan Dickerson, Videographer

WILLIAM J. VIGILANTE, JR.

THE VIDEOGRAPHER: This is the start of DVD number one of the video recorded deposition of William Vigilante in the matter of Gary Bryan Brackin, et al. versus Medtronic, Inc., et al. in the United States District Court for the Western District of Tennessee, Western Division, the docket number is 217-CV-2101.

This deposition is being held at William Cedar, LLC in Philadelphia on 9/14/18 at approximately 10:07. My name is Dan Dickerson. I'm the Legal Videographer Specialist from TSG Reporting. The Court Reporter is Jennifer Billstein-Miller in association with TSG Reporting. Will counsel please introduce yourselves.

MR. HAVERTY: Good morning. Kevin Haverty, William Cedar, for the Plaintiff.

MR. MERRELL: Cliff Merrell on behalf of Defendants Medtronic, Inc. and Medtronic MiniMed, Inc.

WILLIAM J. VIGILANTE, JR.

THE VIDEOGRAPHER: Will the Court Reporter please swear in the witness.

- - -

WILLIAM J. VIGILANTE, JR., after having been first duly sworn, was examined and testified as follows:

- - -

E X A M I N A T I O N

- - -

BY MR. MERRELL:

Q. Good morning, Dr. Vigilante. How are you?

A. Good. Good morning.

Q. We met off the record. I just wanted to ask a few preliminary questions: First, I understand you've had your deposition taken in the past, correct?

A. I have.

Q. About how many times have you been deposed in the deposition?

A. Over 150 times.

Q. And how many times have you testified at trial?

WILLIAM J. VIGILANTE, JR.

A. I think over 40.

Q. Okay. So I can probably dispense and skip most of the preliminary things I might do in a deposition. But you understand if you don't understand my question, just ask me to repeat it or rephrase it; does that make sense?

A. Yes.

Q. And if at any time you need a break, obviously, let me know and we can take a break at any time.

A. Okay.

Q. What did you do to prepare for your deposition today?

A. Multiple things.

Q. And what were those things?

A. I put together the -- I think you guys requested documents in the Notice of Deposition, so I put that together. I reviewed my file. I spoke to my client, Mr. Haverty. I think that's generally it.

MR. MERRELL: Okay. I'm going to go ahead and mark as Exhibit 1 the Notice of Videotape Deposition and hand a copy of that to you.

WILLIAM J. VIGILANTE, JR.

- - -

(Whereupon, Exhibit 1 was marked for identification.)

- - -

BY MR. MERRELL:

Q. I should have a copy of everything, Mr. Vigilante. But if I don't I'll let you know, Mr. Haverty.

And this document, Exhibit 1, is the Notice of Videotape Deposition. I believe you just referenced it. Is this a document you reviewed in preparation for your deposition?

A. Yes.

Q. Okay. And there are a number of document requests beginning on page six; do you see that?

A. Yes.

Q. And they're itemized one through 26 with various letter subparts; do you see that?

A. Yes.

Q. And have you endeavored to collect and bring with you today the materials requested in the deposition notice?

A. Yes.

WILLIAM J. VIGILANTE, JR.

Q. And what have you brought with you today?

A. I brought a disc that contains the responses for -- from the -- the notice.

Q. Anything in addition to the disc?

A. I brought a copy of everything that's on the disc except for the medical records on my laptop.

Q. Okay. And I have a, which I'll mark in a moment, I have a thumb drive of materials that were provided to us along with your expert report.

Do you know whether or not the materials you were provided, the date your report was issued on July 31st, 2018, are those the same materials that are on the disc, or do you think there are some materials on the disc in addition to that?

A. I'm not sure what's on the thumb drive, but I'm going to guess that there's additional documents on the disc.

Q. Do you know whether or not that you've been provided with any documents or depositions following the issuance of your

WILLIAM J. VIGILANTE, JR.

expert report on July 31st, 2018?

A. Yes.

Q. And what depositions or documents do you believe you've been provided since then?

A. I know I received the deposition of a Luci Brackin, a Kristin Bettis and a Rita Weaver.

Q. Have you been provided any other depositions or documents you see there on your laptop?

A. The only one that's -- may not be on the USB drive that's on here is the deposition of I believe Antatoly Aleksandrovich. I initially had that deposition and then somehow or another I lost it in the file and I was sent another copy of it recently.

Q. Okay. Any other documents or depositions you can think of that you have received since July 31st, 2018?

A. I believe I received the affidavit of Jane Hartley after writing -- after drafting my report.

Q. Okay. Anything else you can think of that you received since July 31st, 2018?

WILLIAM J. VIGILANTE, JR.

A. Not that I can recall.

Q. Now, you mentioned several -- several depositions and I want to start with each one. The Luci Brackin deposition, have you reviewed that deposition since receiving it?

A. Yes.

Q. The Kristin Bettis deposition, have you reviewed that deposition?

A. Yes.

Q. And the Rita Weaver Goidel, have you read her deposition as well?

A. Yes.

MR. MERRELL: I'm going to mark as Exhibit 2 a copy of the CD. If you just hand it to me, I'll get a copy made of this for part of the exhibits. During the break, I'll see if I can access it, although I don't have a CD drive.

Not everyone has switched to thumb drives, Kevin.

- - -

(Whereupon, Exhibit 2 was marked for identification.)

- - -

WILLIAM J. VIGILANTE, JR.

BY MR. MERRELL:

Q. You mentioned your preparation for the deposition. A couple of follow-up questions about the notice.

We have a copy of your CV from your expert report on July 31st. Has your CV been updated at all since then?

A. Do you have a date on the CV?

MR. MERRELL: Why don't we go ahead and mark it as an exhibit. Mark as Exhibit 3 a copy of the Curriculum Vitae we have for Dr. Vigilante.

- - -

(Whereupon, Exhibit 3 was marked for identification.)

- - -

BY MR. MERRELL:

Q. I'll hand that to you. It appears to be dated February 25th, 2018.

Do you have any more up-to-date CV than the one that's been provided here?

A. That's my current CV.

Q. Have you brought with you any invoices or billing materials at all?

WILLIAM J. VIGILANTE, JR.

A. I did.

Q. You said yes?

A. Yes.

Q. And are those on a CD or are they hard copy?

A. I brought a copy on the CD. I brought a copy on my computer.

Q. Okay. And would you be able to access a copy of those billing records if I need to ask you questions later?

A. Sure.

Q. Okay. Outside of the CD you provided, are there any other materials that you've relied upon or reviewed in coming to your opinions in this case?

A. Yes.

Q. What would those be?

A. Number one off the top of my head is my experience during my investigation of the Dennert matter, Rachel Dennert matter; number two, my general education, training and background with respect to human factors, product design and to design an assessment of product warnings and instructions.

WILLIAM J. VIGILANTE, JR.

Q. Anything else you can think of, the documents or literature or guidances?

A. Not offhand.

Q. You do have a number of references in your report, which we'll get to later in the deposition, of guidances and literature. Are those on the CD you provided as Exhibit 2 today as well?

A. Yes.

Q. Is there any other literature or guidances or other documents you relied upon in coming to your opinions outside of those that are referenced in your CV -- I'm sorry, those that are referenced in your report and those that are on the CD Exhibit No. 2?

A. I'm not sure I understand what you're asking me.

Q. Okay. I'll try to ask it a different way.

Are you -- are you relying upon any other literature or guidances at all in coming to your opinions here that would not appear on your expert report or on the CD you provided today which we marked as Exhibit 2?

WILLIAM J. VIGILANTE, JR.

A. I think the only other specific reference that I included in the CD was the 2016 version of the FDA's medical applying human factors and usability engineering to medical devices. I think that's the only other specific references -- reference that I included that's not noted in my report.

Q. Okay. And we'll get to this later. But in your report, the guidance you relied upon, was it the 2000 version for human factors that the FDA issued?

A. I believe it's 2000.

Q. Did you --

A. Yes, I'm sorry.

Q. I'm sorry, I didn't mean to cut you off.

A. It's okay.

Q. Was it the 2000?

A. Yes.

Q. Did you -- and you since provided the 2016 guidance, are you relying upon that in any respect in coming to your opinions here?

A. Not necessarily.

Q. Have you conducted any sort of

testing or experimentation at all in this case to come to your opinions?

A. I did.

Q. What sort of testing experimentation did you conduct?

A. I tested my opinions.

Q. And how did you do that?

A. What I did was, I started with essentially applying the scientific method to the different questions I was asked to address. So after talking with Mr. Haverty, we agreed on certain areas that I would look into.

I had done preliminary research, again, based upon my prior experience in the matter. Using that and some other preliminary investigation I created, I came up with three questions that I wanted to address. They are listed in my report. The first is whether or not Medtronic conducted an adequate human factors analysis of its product and whether its failure to do so caused or contributed to Pamela Brackin's injury and death; whether Medtronic provided adequate instructions and warnings with its Paradigm reservoir and

infusion set regarding the hazard associated with the potential lockage of the P-Cap connector vent. And then the last hypothesis was whether Medtronic, whether their failure to provide adequate instructions and warnings regarding the hazard associated with the potential blockage of its P-Cap connector vent was improper in the manner which caused or contributed to Ms. Brackin's injury and death.

So for the first, I looked at whether or not there was a hazard associated with the use -- foreseeable use, I should say, of the P-Cap connector, the infusion set, the reservoir, et cetera. Based upon information from discovery information provided in the case, specifically Randy Adair and some of the other information that was produced, I concluded that there was, in fact, a hazard associated with the unattended delivery of insulin resulting from the blockage of P-Cap connector vents.

The second thing I looked at is whether Medtronic conducted a proper risk and human factors analysis. So one of the first

things I did was I looked at the standard of care for both product design, development and the design development of medical devices to see what was the standard of care for product designers such as Medtronic and designing and developing a product such as the P-Cap connector, the reservoir and -- and the infusion set.

So I lay out those specific steps and specific requirements in my report under section E2. Then using the discovery material provided in the case, I looked at what Medtronic had done both when they were developing the product in the 1990s, late '90s, early 2000s and up to Mrs. Brackin's event, and compared them, tested them against the standard of care, and found that they were, in fact, deficient. Again, that's noted through section E2 in my report.

Based upon my testing of my apotheosis, I came to my opinions with respect to that topic. I then looked at questions related to -- issues related to failure to warn and instructions. Again, that's laid out in

section E3 in my report.

What I looked at again was the standard of care for the design and development of warnings and instructional material. I looked at the information provided by Medtronic, both pre and post-2013, including the Getting Started Guide that was relied upon by the Brackins in using the -- using the product.

I tested what Medtronic had done based upon their records, deposition testimony, to the standard of care, and came to my opinions with respect to that topic.

I then looked to see whether or not adequate instructions and warnings could have and should have been designed in development, and I addressed that in section E4 in my report. To do that, I looked at what the standard of care was for the design and development again of warnings and instructions, and developed an alternative warning and instructions set based upon those standards, guidelines and recommendations, and then came to my conclusions with respect to that topic.

Q. Okay. And that information you just provided in your testimony, is that all included in your expert report?

A. Yes.

Q. Have you ever handled a Medtronic 523 insulin pump?

A. I don't know if I handled the 523 insulin pump, but I handled a similar insulin pump in my investigation of the Dennert matter. And I don't recall exactly which model number it was, but it was a similar pump.

Q. Since handling the insulin pump involved in the Dennert case, have you handled another insulin pump at all?

A. I have not.

Q. Have you handled the reservoir at issue in this case?

A. The specific reservoir issue in this case, I was not provided with.

Q. Have you handled the specific infusion set at issue in this case?

A. I have not. I'm not aware of them being available.

Q. All right. And I'll probably ask

another question. Have you handled an exemplar of the reservoir at issue in this case?

A. I have examined an exemplar of the reservoir infusion set. I don't know that they were the specific batch or model number of the one used by Mrs. Brackin.

Q. And when did you -- when did you do that?

A. Through my investigation of the Dennert matter.

Q. So since the Dennert matter, have you handled an insulin pump infusion set or reservoir?

A. I have not.

Q. In this specific case, did you conduct any sort of experimentation with an insulin pump or reservoir or infusion set -- I assume not since you haven't handled them since then?

A. The only experimentation I do is look through the user guides, Getting Started Guides and IFUs to understand how they worked to ensure that they were similar to my experiences in the Dennert case.

Q. Okay. And when you went through those, I take it, though, in this particular case you didn't utilize an insulin pump, reservoir, infusion set?

A. I did not physically interact with or handle a reservoir, infusion set or pump in my investigation of this case. I relied upon my experience in the Dennert matter.

I need to append that answer. Also, I relied upon my review of the relevant Getting Started Guide, pump User Guide and IFUs for the infusion set and reservoir to ensure that they, with respect to the topics I was addressing, were the same.

Q. And just kind of break that down, did you -- are you saying that you looked at the specific infusion set and reservoir IFU in this case and compared them to ones you reviewed in the past?

A. I did.

Q. Okay. And did you look at and review the User Guide and Getting Started Guide for the insulin pump here to compare it to prior getting started guides and user guides you've

used in the past?

A. For the user pump, I did. I did not -- I do not recall having a Getting Started Guide in the Dennert matter.

Q. And when you reviewed the Getting Started Guide, did you utilize the version that Plaintiff actually had and produced with highlighting in it?

A. I had a copy, but I don't believe I have the original, but I had a copy of it.

Q. I asked you earlier about what you did to prepare for your deposition. I wanted to break that down a little bit.

Part of the preparation you did for this deposition was speaking with Mr. Haverty; is that correct?

A. Yes.

Q. When did you speak with Mr. Haverty in preparation for the deposition?

A. Yesterday.

Q. How long did you speak with Mr. Haverty?

A. I'm going to approximate between 15 minutes and a half hour.

WILLIAM J. VIGILANTE, JR.

Q. Was that the only time you spoke with Mr. Haverty to prepare for this deposition?

A. I believe -- I believe so.

Q. Did you speak with anyone else to prepare for the deposition today?

A. I did not.

Q. And did you spend any time reviewing materials or documents to prepare for the deposition today?

A. Yes.

Q. How long do you think you spent to do that?

A. In total, yesterday I probably spent a little over three hours.

Q. Did you spend any time prior to yesterday preparing for the deposition?

A. I don't recall.

MR. MERRELL: I'm going to mark as Exhibit No. 4 and hand to you an email and letter provided by Mr. Haverty on July 31st, 2018 disclosing you as an expert.

I have a copy for you.

- - -

WILLIAM J. VIGILANTE, JR.

(Whereupon, Exhibit 4 was marked for identification.)

- - -

BY MR. MERRELL:

Q. Do you understand you were disclosed as an expert on behalf of the Plaintiffs on July 31st, 2018?

A. I don't know what date I was disclosed, but it was my understanding that I would be.

Q. Do you recall when you were first contacted regarding this case by Plaintiff's case?

A. Not offhand.

Q. Do you know who initially contacted you about this case for Plaintiffs?

A. I think it was Mr. Haverty, I'm pretty sure it was.

Q. Do you know if it was this calendar year, was it in 2018?

A. Offhand, I don't know.

Q. Do you have your billing records available?

A. Yes.

WILLIAM J. VIGILANTE, JR.

Q. When is the first notation you have for time you spent on this case?

A. It looks like July 23rd, 2018.

Q. And how much time did you bill that day?

A. Just about an hour.

Q. Do you know if that was reviewing the file or speaking with somebody?

A. Both.

Q. And who did you speak with that day?

A. Mr. Haverty.

Q. So prior to July 23rd, 2018, you did not perform or conduct any work in this case; is that accurate?

A. Nothing that I billed for.

Q. Do you believe that you conducted any activities or work prior to July 23rd, 2018 that you did not bill for?

A. I would have spoken with Mr. Haverty about the case prior to that.

Q. Okay. What amount of time, if any, do you believe you would have spent on this case prior to July 23rd, 2018?

A. I don't know. I can tell you that

WILLIAM J. VIGILANTE, JR.

the inquiry for the case was in June of 2018.

Q. And what do you mean by "inquiry"?

A. When Mr. Haverty called to speak specifically to me about the case.

Q. So you were first contacted about this case in June of 2018; is that accurate?

A. Yes.

Q. And you were contacted by Mr. Haverty?

A. Specifically, regarding this case, yes.

Q. How much time did you spend on this case between July 23rd and July 31st to prepare your expert report?

A. One more time?

Q. How much time did you spend to prepare your expert report between July 23rd, 2018 and July 31st, 2018?

A. So it looks like the total time I billed for is 7.75 hours or thereabouts.

Q. Okay. So the total time you spent in preparing your expert report in this case was about 7.75 hours; is that correct?

A. No.

Q. Okay. And can you explain that.
A. That's the time I billed.
Q. Okay. So the total time that you billed in preparation for your expert report in this case is 7.75 hours; is that correct?
A. As of July 31st, 2018, that's correct.
Q. What is the -- in your -- in your billing information that you have in front of you, what is the last date that you have there for time you've either billed or time that you've noted as time to bill?
A. Bill time, the last entry was 7/31/2018.
Q. And did you send that bill to Mr. Haverty?
A. Yes.
Q. After July 31st, 2018, have you kept records of how much time you spent in this case?
A. I would have logged time that I spent on this case since then.
Q. Do you have those in front of you or available to you?

A. I do not.
Q. Do you have an estimate of about how much time you spent on this case since that bill on July 31st, 2018?
A. I know it's more than a little over three hours, but I don't know where the high end is.
Q. Is it less than ten hours; do you think?
A. I don't know.
Q. Following the issuance of your report on July 31st, 2018, what work did you do in this case?
A. There were additional depositions that were provided to me. I think I mentioned them a little earlier in the deposition. Those included exhibits. So other than reviewing those documents and preparing for the deposition, I don't have a specific recollection of what other work I may have done.
Q. And your review of information and depositions since the issuance of your report on July 31st, 2018, has that changed or altered

anything that you put in your expert report initially?
A. It did not.
MR. MERRELL: I'm going to mark as Exhibit 5 the copy I have of your expert report.
- - -
(Whereupon, Exhibit 5 was marked for identification.)
- - -
BY MR. MERRELL:
Q. And I'll ask you a few questions and then I want to turn to your CV and I'll come back to this, but I'm just trying to cover and address all of the materials you reviewed as part of this case.
Can you look at page three of your report.
A. Sure.
Q. There's a list of available materials on page three; do you see that?
A. Yes.
Q. Is this list a complete list if you add the more recent depositions you received,

the Luci Brackin deposition, the Weaver deposition and the Bettis deposition?
A. A complete list of what?
Q. Of the materials that were available for you to review to provide your opinions.
A. Specifically, for this case, I believe so.
Q. I notice your -- the list of deposition transcripts, I don't see the deposition transcript of Afshin Bazargan; is that a deposition you reviewed as part of this case?
A. I don't believe so.
Q. I also don't see Suzanne McConnell-Montalvo; is that one you reviewed as part of your review in this case?
A. I don't know if that one was -- I've included it in my file. I had reviewed her deposition dated June 23rd, 2015. I don't know why I didn't include it in my material available.
Q. Okay. So although it's not included in the available materials, that is one you have reviewed?

A. I had reviewed, yes.
Q. Have you reviewed the deposition of Dr. Gosmanov?
A. I don't believe I have.
Q. You also list under Available Materials, various medical records; do you see that?
A. Yes.
Q. Do you have -- do you know if you have a complete set of medical records in this case?
A. I do not know that.
Q. Which medical records do you believe you've reviewed?
A. I don't recall exactly what medical records there were. I did not include them on my laptop because they were rather -- there was a lot of them, but I did include them on the disc.
Q. Sorry, keep going.
A. So I don't recall spending any great amount of time and energy going through all of her medical records regarding pre and post-incident treatment.

Q. Do you know about how much time you spent looking at medical records?
A. I do not.
Q. Do you think it was less than three hours?
A. I would imagine so.
Q. Do you think it was less than an hour?
A. I -- probably.
Q. Were you given any guidance at all as to particular materials, depositions to focus on in this case?
A. Well, I imagine that the ones that were provided with I was supposed to -- well, I don't know what Mr. Haverty's intent was.

But the material that I was provided with is the stuff I looked at. Other than the various medical records, I typically don't get involved in pinnacle issues related to pre and post-treatment.
Q. With respect to the deposition, did you read every page of the depositions you were provided?
A. I skimmed Antatoly's current

deposition, so I can't say that I got every page.
Q. What about the Vardi deposition, did you -- have you reviewed every page of that?
A. I don't recall at this point.
Q. And the -- this recent Anthony Vicente's deposition, did you review every page of that?
A. I can't recall if I had done that either.
Q. Do you know if you reviewed all of Mr. Brackin's deposition?
A. Yes.
Q. Do you know if you read all of Mr. Duarte's deposition?
A. John Duarte, I had.
Q. Okay. Have you reviewed all of Karen Fisk's deposition?
A. I have.
Q. And have you reviewed all Mark Curtis's deposition?
A. I have.
Q. And have you reviewed all of the Rabi Gharabli deposition?

A. I have.
Q. Have you reviewed all of Randy Adair's deposition?
A. Yes.
Q. Now, with respect to the medical records, were there certain ones that you were asked to focus on or look at?
A. I don't recall being asked to look at or focus on any specific medical records.
Q. How did you determine which medical records to look at or review?
A. I opened the files to see what they were addressing, and if I didn't find them relevant, I didn't spend a great time -- great -- great amount of time looking at them.
Q. Were there any particular medical records that were important to your opinions that you reviewed that you can think of?
A. I don't recall certainly everything that was in there. I recall either between the depositions and maybe some of the medical records identifying when Mrs. Brackin was recommended to use the subject pump, when she began using the subject pump, but other than

that, I don't recall seeing anything relevant.
Q. Have you reviewed the testing that Medtronic conducted on the insulin pump, the reservoir and the infusion set in this case at all?
A. What kind of testing?
Q. Well, I'll represent to you that Medtronic conducted testing specifically looking at the functionality of the insulin pump at issue here, Ms. Brackin's insulin pump, the reservoir and the infusion set. And I'm asking whether or not that's testing -- the results of the testing is something you reviewed in coming to your opinions?
A. Is that post-incident testing?
Q. This testing would have been post-incident, yes.
A. Nothing is coming to mind at the moment.
Q. And perhaps, I don't know if this will jog your memory or not, but the testing was conducted in May of 2017. Is that anything that sounds familiar as something you reviewed?
A. I don't recall that material offhand.

Q. I wanted to turn back to your CV. I forgot what we marked it as an exhibit. I think it may be four.
A. Three.
Q. And first of all, what is your hourly rate you're charging?
A. My current hourly rate is 395 an hour for all case-related work, except for videotaped testimony, which is I charge at 495 an hour.
Q. And the videotape deposition, do you charge that $495 an hour as, as a premium or above if it was not videotaped; is that accurate?
A. If it was a non-videotaped deposition, it would be 395 an hour.
Q. And turning to your CV, what is the -- what is the current company you work at?
A. I work technically for Vigilante Consulting, LLC.
Q. And I notice that your CV says Vigilante Forensic. Is there a distinction at all?
A. Well, legally, Vigilante Forensic is

doing business as Vigilante Consulting, LLC, so it's registered with the state as a d/b/a.
Q. And prior -- well, strike that.
Did you begin the Vigilante Consulting, LLC in 2015?
A. Yes.
Q. And your work for Vigilante Consulting, has that all been litigation work?
A. No.
Q. Okay. What other work have you done with Vigilante Consulting?
A. So I run the forensic investigation side of the business through Vigilante Forensic. I run traditional consulting through Vigilante Consulting, LLC.
Q. With respect to the Vigilante Consulting, how much work have you done that's non-litigation consulting?
A. It's probably, depending upon what projects I am or not involved in, a small part of overall work.
Q. Okay. Would you say that the litigation consulting you do that is serving as an expert report, is that 95 percent plus of

the work you've done with Vigilante Forensic -- well, strike that. Let me ask it a different way.
Would you say that your work since you started Vigilante Consulting in 2015, that 95 percent of your -- 95 percent plus of your work has been litigation consulting as an expert?
A. Under both Vigilante Consulting and Vigilante Forensic, it's probably about that.
Q. Have you done any consulting for any medical device companies since 2015 with Vigilante Consulting?
A. I have not.
Q. Prior to your work with Vigilante Consulting, were you at Robson Forensic?
A. Yes.
Q. And were you there from 2003 to 2015?
A. Correct.
Q. And your title there was associate?
A. That's my understanding.
Q. Were you ever made a principal there?
A. No.
Q. The work you did at Robson Forensic,

was it similar to the work that you're doing now at Vigilante Consulting and Vigilante Forensic?

A. Yes.

Q. While you were at Robson Forensic from 2003 to 2015, was the amount of litigation expert work you did, was that 90 to 95 percent of the work you did?

A. I think over time, over the -- I don't know how long I was there, 13 years or so, approximately, that's what it was approximately. That was billable time.

Q. And you say "billable time," would there have been non-billable time where you prepared proposals, or what would the non-billable time be?

A. Partly that. I also was an area manager for the company for approximately the last five years I was with them, so I had managerial responsibilities over the Philadelphia office, including employment, marketing, et cetera.

I was also the area -- or the practice group leader for the human factors

practice group, so I had a lot of responsibilities related to peer reviewing other people's work, hiring and -- and so forth with regard to other human factors, experts promoting the practice, billing the practice, et cetera. So it was a lot of non-billable time related to those two other titles or positions.

Q. What is your approximate income then with Vigilante Consulting over the last year?

A. I don't know offhand.

Q. You don't have any estimate at all?

A. I don't have a good estimate, and it's confidential, so I can't provide it even if I did have an estimate.

Q. So the figure itself would be confidential?

A. Yes.

Q. Even without regard to where the income came from?

A. Yes.

Q. Your work with -- well, strike that.

Prior to Robson Forensic, you were at A-R-C-C-A; is that correct?

A. I was an independent contractor for a company called ARCCA, A-R-C-C-A.

Q. And what sort of work did you do at ARCCA?

A. Forensic investigations.

Q. Was that also primarily litigation work?

A. I believe so. You know, I don't remember every project I did for -- for ARCCA, but they were all forensic related. Whether or not they were all in litigation, I can't say, but I don't recall.

Q. Was 95 percent plus of the work you did at ARCCA, was it litigation work?

A. I have no idea.

Q. So I guess it was a long time ago. And then prior to that you worked at International Business Machines Corporation from 1998 to 2003?

A. No.

Q. Well, I'll just ask you a non-leading question.

Did you work -- prior to ARCCA, did you work at IBM?

A. So it's a little bit confusing. If you allow me, I can explain it.

Q. Yeah, absolutely.

A. Okay. So I worked for the IBM Corporation from 1997 until July 2003 when I left IBM to join Robson Forensic, slash, Robson Lapina at the time.

In approximately August/September 2001, while I was employed by IBM, I worked for ARCCA as an independent contractor, essentially, moonlighting with the permission of my management staff at IBM, doing forensic consulting. So my time at ARCCA overlapped my time at the IBM Corporation, and my time at ARCCA ended also when I joined Robson Forensic in July 2003.

Q. Your litigation work you've done over the years for these various entities, do you have a percentage that was plaintiff versus defendant that you can think of?

A. Historically, it's probably about 60/40, plaintiff/defendant.

Q. The 60 percent of the work historically has been for the plaintiff?

A. Yes.
Q. Since you started Vigilante Forensic, has the same held true?
A. I can't say it's exactly the same, but it's approximately. I think maybe about 65 plaintiff, 35 defendant with Vigilante Consulting or Vigilante Forensic.
Q. I take it you've never worked for a medical device company?
A. Not that I'm aware of.
Q. And you never worked at the FDA?
A. I have never worked at the FDA.
Q. And you've never done any consulting for the FDA regarding medical devices?
A. Not with regard to medical devices, with regard to prescription and non-prescription medication labeling.
Q. But no work with the FDA regarding medical devices; is that accurate?
A. That's correct.
Q. And have you ever done any consulting at all for a medical device company?
A. Not that I'm aware of.
Q. Have you ever -- strike that.

So you've never been asked by a medical device company to write labeling, for example, or instructions?
A. I have not.
Q. And you've never been asked by a medical device company to prepare warnings for a medical device?
A. I have not.
Q. You've never been asked by a medical device company to evaluate their warnings, labeling or instructions?
A. I don't believe so.
Q. And you've never been asked by the FDA to evaluate the warnings, labeling or instructions of a medical device?
A. I don't believe so.
So I have to amend one or two of those answers. With regard to a medical device company and whether I've been asked to either draft or assess their warnings and instructions, I don't know. I can't say that I haven't.
In my research during graduate school, we were doing work for the Drug

Information Association. I can't say that the folks that were a part of that organization that we were interacting with were not involved in medical device manufacturing, and part of that work was the research related to warnings and instructions for medical -- excuse me, drug-related products.
Q. That would have been back in 2000/2001?
A. It would have been from, I would say, '97 to 2001.
Q. So this work you did from 1997 to 2001, you don't know whether or not it involved a medical device company at all?
A. I don't recall any specific devices, but I can say it didn't.
Q. Uh-hum. The work that you did, do you recall there being prescription drugs or over-the-counter drugs that you looked at?
A. I know that my research specifically focused on over-the-counter medication labeling and prescription drug advertising.
Other projects that I worked on, one that was in the cognitive ergonomics

laboratory at North Carolina State University, I don't recall all of them. There were other medical and drug-related products that were looked at and other studies that I helped with.
Q. Okay. So in this time period from 1997 to 2001, you don't know whether it involved a medical device company, correct?
You don't know whether it involved a medical device company?
A. I can't say that it didn't.
Q. Since then, have you had any consulting work for a medical device at all?
A. Not that I'm aware of.
Q. I take it you've never been involved in the design process of a medical device?
A. Not that I'm aware of.
Q. You've never been involved in a risk analysis for a medical device company?
A. On behalf of a medical device company, that's correct, but I have done a risk analysis of a medical device.
Q. The risk analysis you've done for a medical device, is that on behalf of a plaintiff in litigation?

A. Yes.
Q. And how many times have you done that?
A. In the Dennert matter and in this one, were the only two insulin pumps that I can recall, and I don't recall if I've worked on another medical device matter in the -- in my forensic practice prior.
Q. Okay. And the Dennert matter was around 2016?
A. I don't recall specifically when that was, but it's at least a couple of years.
Q. Okay. Prior to the Dennert matter, though, you can't, sitting here today, you can't think of any other medical device litigation where you were asked to analyze the risk or labeling of a medical device?
A. The only one that I can think of was an over-the-counter device for pain relief, but I don't recall any other prescription-type medical device products offhand.
Q. Okay. And you've never been involved in a 510(k) application or submission for a medical device?

A. Not that I'm aware of.
Q. And you've never been involved in a premarket approval submission or process for a medical device?
A. I don't believe I have.
Q. And you never performed a risk analysis or design validation according to FDA regulations?
A. On behalf of a manufacturer, I don't believe so.
Q. Well, have you ever applied FDA regulations for any risk analysis or design verification project?
A. I'm sorry, you're going to have to repeat that.
Q. Okay. Have you ever, in any context, have you ever been asked to apply FDA regulations to evaluate a risk analysis?
A. I'm not sure that that question makes sense, so I'm going to have to ask you to rephrase it.
Q. Okay. Have you ever been -- have you ever been asked to evaluate a specific medical device and its potential risks and hazards

under FDA regulations?
A. I'm not sure what you're asking me. So under FDA regulations that it needs to be done during design and development, or are you asking --
Q. I'll rephrase.
A. I'm sorry, go ahead.
Q. Sure. I'll just rephrase it.
Well, let me ask you this: Do you consider yourself to be an FDA regulatory expert with regard to submissions of PMA or 510(k) or product?
A. I do not hold myself out as an expert in regulatory submissions.
Q. Okay. Do you hold yourself out as an FDA regulatory expert on the design and development process for medical device?
A. I do not hold myself out as a regulatory expert.
Q. Do you hold yourself out as a -- strike that.
Do you hold yourself out as an FDA regulatory expert in any context?
A. In any context, I don't know. I

wasn't planning on providing opinions regarding a regulatory requirement in this case.
Q. So you do not have any opinions in this case as to whether or not Medtronic or MiniMed complied with FDA regulations or requirements?
A. I wasn't planning on it.
Q. Sitting here today, you haven't formed any opinions that -- about whether Medtronic complied with any FDA regulations?
A. I haven't given it any thought. So I wasn't asked to address it and I wasn't planning on addressing it.
Q. And I take it you're not going to provide any opinions as to whether Medtronic complied with FDA labeling requirements?
A. I wasn't asked to look to determine whether or not Medtronic complied with FDA labeling requirements.
Q. Are you --
A. Regulatory requirements.
Q. Sorry, I didn't mean to cut you off.
Are you leaving the -- that aspect of this case, the FDA regulations and

requirements, are you leaving that to other experts to address?

A. I'm not sure that it was a question in the case. If it is, I wasn't asked to address it, and I don't know who is addressing it.

Q. Okay. So that hasn't been part of your analysis, whether or not Medtronic and the medical device at issue in this case complied with any FDA regulations or requirements?

A. I have not been asked to address whether Medtronic complied with any FDA regulations.

We've been going about an hour. Would you like to --

Q. Absolutely.

A. -- take a break for a little bit?

Q. That's fine.

A. Unless there was a better point that you wanted to break at?

MR. MERRELL: No, that's fine.

THE VIDEOGRAPHER: The video time is now 11:05. We are going off record. This now ends DVD number one.

- - -

(Whereupon, a short recess was taken.)

- - -

THE VIDEOGRAPHER: This begins DVD number two. We are now back on record. The video time is 11:16.

BY MR. MERRELL:

Q. Dr. Vigilante, you have a Ph.D. from North Carolina State University; is that correct?

A. That's correct.

Q. What is your Ph.D. in?

A. Ergonomics psychology.

Q. And I think you testified before is it, technically, is it a doctor of philosophy at that school?

A. Yes.

Q. And prior to that, you received from North Carolina State University a Master's in Science in Psychology and Ergonomics; is that correct?

A. Yes.

Q. And then you also have a Bachelor's

of Science and Psychology Cognitive Track at University of Scranton, correct?

A. Correct.

Q. And just for clarity, you don't have a medical degree?

A. I do not.

Q. You don't have an engineering degree?

A. I do not.

Q. You don't have a, for example, biomedical engineering degree or anything like that?

A. I do not have a biomedical engineering degree.

Q. You wouldn't consider yourself to be an engineering expert?

A. It depends on the topic.

Q. Okay. You wouldn't consider yourself to be a design expert in engineering?

A. It depends upon the topic.

Q. What aspects of engineering would you consider yourself to be an expert in?

A. My expertise is in the design of controls and displays. That is the user interaction of products. That's what the field

of ergonomics and human factors is focused on. It's a design-based science.

At the IBM Corporation, I was categorized as a human factors engineer. Oftentimes, in my field, at least in the past, was referred to as ergonomics -- or, excuse me, engineering psychology or cognitive engineering.

So from a litigation, legal perspective, I'm not a professional engineer, but I do have training in product design, particularly with respect to user interface, and controls, displays, instructions and warnings.

Q. Is your expertise in engineering, is it limited to ergonomics and human factors?

A. Yes.

Q. And obviously, you're not an endocrinologist?

A. I am not.

Q. And not a neurologist, correct?

A. I am not.

Q. And I take it you're not here to provide any sort of clinical or medical

opinions in this case; is that correct?
A. That is correct.
Q. And you're not going to provide any opinions in this case as to medical causation; is that correct?
A. I was not going to provide any opinions regarding medical causation.
Q. I take it from your report -- well, strike that.
Your report focuses primarily on instructions and labeling and human factors issues; is that correct?
A. It does address those issues.
Q. Are you going to be providing any design opinions in this case?
A. Other than the fact that the design allowed for -- created the potential for a common slip or lapse to result in a catastrophic injury, and therefore it should have been fixed through design consistent with the safety hierarchy and basic design guidelines, recommendations and basic human factors guidelines and recommendations.
Q. Okay. But you never designed a

medical device, correct?
A. I have not.
Q. Are you going to be providing an opinion as to an alternative design for the infusion set at issue here?
A. I was not providing an opinion regarding alternative design. It's my understanding that there were alternatives, but I'm not providing that -- that opinion.
Q. Okay. So I take it you would leave the issues of alternative designs and alternative membrane material, for example, you would leave that to Mr. Klimowicz and other experts in the case?
A. I am not addressing the design of alternative membranes. I would assume that other experts are addressing that.
Q. Okay. You're -- you're addressing instructions for use and labeling with respect to the design components you discussed; is that accurate?
MR. HAVERTY: Objection.
THE WITNESS: That is part of my analysis.

BY MR. MERRELL:
Q. I think you've been asked some of these questions before, but I just want to confirm nothing has changed since your last deposition.
Are you familiar at all with a design history file for a medical device?
A. Any medical device or the specific ones involved in this case?
Q. Generally speaking, a design history file for a medical device.
A. I don't believe so.
Q. Are you familiar with a medical device history for a medical device generally?
A. Not offhand.
Q. And you don't know what regulations govern a design history file for a medical device, correct?
A. Not offhand.
Q. Okay. And you never maintained or created a design history file for a medical device?
A. Not that I'm aware of.
Q. Other than the 2000 and 2016

guidances on human factors for a medical device issued by the FDA, are you familiar with any other FDA regulations or guidances with respect to medical devices?
A. Offhand, I don't recall any. Specifically, those were the two that I pointed to in my report.
Q. So in your report, you don't point to any other FDA guidances or regulations other than the 2000 and 2016 human factors guidances?
A. That's correct.
Q. And is it correct that the first time you reviewed the 2016 guidance was part of your review in the Dennert case?
A. I don't recall what my testimony was, so whatever it was in the Dennert case, I would stand by it.
Q. Okay. Maybe that's a good question. Do you stand by the testimony you previously provided on two separate dates for the Dennert case?
A. As far as I know.
Q. You don't have any changes or retractions at all for those depositions?

A. I certainly don't recall what questions were asked or answers that were provided, but there's nothing that stands out that I wanted to correct on the record.

Q. Okay.

A. At this moment.

Q. And I take it you don't recall ever reviewing the 2000 and 2016 guidance on human factors issued by the FDA prior to your involvement of the Dennert case?

A. At this point, I don't recall.

Q. And given your answer, I take it you never reviewed the -- other than these two guidances, you never reviewed any FDA regulations on medical device labeling or instructions for use?

A. I don't believe that's correct, but I don't recall anything specific offhand.

Q. Okay. And in what context do you think you might have reviewed some other regulation other than these two guidances?

A. It may have been done in my research for either the Dennert case or this case or another case. I don't recall offhand the

specific regulation.

Q. Okay. Sitting here today, you can't point to another regulation or guidance relating to medical devices on labeling and instructions for use other than those two guidances we've already discussed from 2000 and 2016?

A. Not offhand.

Q. And are you familiar with ISO 14971 application of risk management for -- to medical devices?

A. I don't recall if I've reviewed that standard or not.

Q. It's not something you've applied in this case, though?

A. It is not.

Q. You have applied ANSI standards in this case; is that correct?

A. I did reference a specific ANSI standard in this case.

Q. Your references are contained on page 25 of your expert report; is that correct?

A. That's correct, specific references.

Q. And these references as one through

11 are ones that appear as references throughout your report; is that correct?

A. That's correct, they're cited in the report.

Q. One of the -- the ANSI one I see here is Z535.6, product safety information on product manuals, instructions and other collateral materials; do you see that?

A. Yes.

Q. Do you know whether or not this would apply to a medical device?

A. It was part of the standard of care industry knowledge at the time that the Getting Starting Guide was manufactured and provided with the subject pump.

Q. Do you know if the FDA -- I'm sorry, keep going.

A. And the training of the subject pump.

Q. Do you know if the FDA utilizes the ANSI standard you've identified here in its regulation of the labeling of medical devices?

A. Offhand, I do not.

Q. And you've never performed a risk -- strike that.

You never performed a formal risk analysis for a medical product?

A. On behalf of a medical device manufacturer, I don't believe so.

Q. The only risk analysis you would have performed would be on behalf of a plaintiff in a litigation; is that accurate?

A. The only ones that I'm aware of would have been done in conjunction with my investigation of a forensic -- excuse me, a forensic investigation of an incident that occurred involving a product, medical product.

Q. And would that risk analysis for those circumstances for a medical device, would that have been looking at specific issues or the entire risk analysis for the device?

A. Specific issues.

Q. So you haven't done a comprehensive risk analysis for a medical device in any context?

A. I have not. And it's not necessary for the work that I'm doing.

Q. Are you aware or familiar that the insulin pump at issue in this case, the 523,

was approved by the FDA through the PMA process?

A. It's my understanding it was.

Q. And are you aware that the reservoir and infusion set were cleared through the 510(k) process by the FDA?

A. I don't recall which specific process they went through.

Q. Does the fact that it was PMA approved, the devices were PMA approved or 510(k) cleared by the FDA, does that have any impact on your opinions at all?

A. It does not.

Q. Does the FDA's view of the safety and effectiveness of these devices and their labeling, does that have any impact on your opinions?

A. Specifically, on my opinions, they do not.

Q. So you come to your opinions regarding the labeling and instructions for use and the safety and efficacy of these products based on your analysis, and the FDA's review is not germane to it; is that accurate?

MR. HAVERTY: He's not making any judgments about safety and efficacy.

THE WITNESS: I conducted an independent investigation independent from what the FDA may or may not have done.

BY MR. MERRELL:

Q. Okay. That's a fair point. You are not actually making an analysis of the safety and efficacy of these products; is that correct?

MR. HAVERTY: As the FDA understands that.

THE WITNESS: Not with respect to the manner in which the FDA would understand it.

BY MR. MERRELL:

Q. Okay. So if you review or analyze safety or efficacy, it's not in the same manner that the FDA does it; is that correct?

A. I did not do an exhaustive investigation of what the FDA requirements were or what their processes or what their thought was.

I looked at it from a product

safety standpoint, a human factors standpoint, and came to my opinions based upon my training, my education and my experience in the standard of care for a product designing introducing a product into the market that's going to be used by the typical or average consumer such as the Brackins.

MR. HAVERTY: Just note my objection to the record that the FDA does not make safety and efficacy determinations as to 510(k) products.

MR. MERRELL: Okay. I'll note your objection, whether or not we agree on it, that's fine.

BY MR. MERRELL:

Q. And in this case, you haven't done an analysis of efficacy regarding the insulin pump at all; is that correct?

A. Regarding the pump, I don't believe I have any opinions regarding the pump.

Q. So you don't actually have any opinions at all regarding the insulin pump; is that correct?

A. The pump itself, I do not.

Q. Okay. And I think that's helpful -- which means I probably don't have to cover -- so you're not -- strike that.

You're not here to provide any opinions at all about the 523 insulin pump and whether or not it had a malfunction or whether or not it was defective or anything like that; is that correct?

A. I'm not providing opinions as to whether or not the pump malfunctioned or if the pump itself was defective.

Q. Okay. And you don't have the qualifications to really address that; is that correct?

A. I don't know if I do or do not because I wasn't asked to address it.

Q. Okay. And you have not addressed that, correct?

A. I have not addressed whether the pump was defective or not.

Q. And you haven't addressed whether there was actually a malfunction in this case, correct?

A. With respect to the pump, I have not.

WILLIAM J. VIGILANTE, JR.

Q. And sitting here today, you don't know whether or not the FDA found the particular pump or infusion set or reservoir to be safe and effective?

MR. HAVERTY: Objection.

THE WITNESS: I do know that the FDA -- I don't recall the exact letter that I saw from the FDA regarding the system and the problems with it.

I do know that Medtronic did initiate a recall of the infusion set and/or reservoirs I think in late 2017, but I did not go into investigation of what the FDA did or did not do other than that.

BY MR. MERRELL:

Q. Okay. And you haven't -- you haven't looked, for example, at any FDA warning letters or anything like that with respect to your analysis in this case?

A. I do recall one letter from the FDA regarding the infusion set or reservoir and/or -- well, I'll title it as pump system. That's -- offhand, that's the only one that I

WILLIAM J. VIGILANTE, JR.

recall.

Q. Okay. Have you relied upon that at all in coming to your opinions in this case?

A. I did not.

Q. And you're not holding yourself out as an FDA expert with respect to matters in this case; is that correct?

A. Yeah, I'm not holding myself out as a regulatory expert in this case, I think that's the best way to put it.

Q. Okay. I want to turn to another topic just briefly. I'm going to ask you about your opinions relating to the temporary blocked vent issue. Do you understand what I mean when I refer to it as that?

A. I believe so.

Q. Okay. In your report, are you making a statement or are you coming to an opinion based on your own review and analysis of whether or not there actually was a temporary blocked vent with respect to Mrs. Brackin's infusion set?

A. That's my understanding.

Q. Okay. So you say it's your

WILLIAM J. VIGILANTE, JR.

understanding. What is the understanding based on?

A. My understanding is based upon my conversations with Mr. Haverty and my understanding of the events.

Q. And have you conducted any actual experimentation or testing on the infusion set or the reservoir infusion pump to determine whether there actually was a temporary blocked vent?

A. I have not inspected and/or tested the specific infusion set and/or pump involved in the matter.

Q. Okay. What is the -- what evidence is there specifically you point to for you to come to say that it's your understanding there was a temporary blocked vent?

A. Yeah, it's based upon my -- my conversations with Mr. Haverty, which are consistent with what I saw based upon the notes that were taken by Mr. Brackin after the incident regarding what was done and recorded by the pump regarding the fill the night before, and the other records that were

WILLIAM J. VIGILANTE, JR.

produced with the pump or from the pump.

Q. Is it simply that there was a fill the night before that supports your understanding that there was a temporary blocked vent?

A. In conjunction with the fact that she was not -- I believe there was no record of her -- Mrs. Brackin, I should say, administering any independent boluses through the evening and morning.

Q. Do you know how much insulin the insulin pump delivered on January 15th, 2016?

A. Offhand, I do not. I think that my understanding is that the daily dosing history showed a total daily dose of 26.825 units delivered on January 14th and 132.7 units on January 15th following the reservoir fill and infusion set change.

Q. Okay. And the 132.7 units on January 15th, does that come from the screen on the insulin pump, the screen shot?

A. It came from my understanding from Brackin Exhibit 22.

Q. And do you recall offhand if that's

his notes or --

A. I'd have to go back and find the exhibit.

Q. Okay. I'll probably try to do the same. I don't have the exhibit numbers memorized.

MR. HAVERTY: It is the screen shot.

BY MR. MERRELL:

Q. It is the screen shot. Okay.

Have you looked at the screen shots of the insulin pump?

A. If they were part of the exhibits, I have.

Q. Okay. And you testified earlier that you did not review the testimony of Afshin Bazargan; is that correct?

A. I have not.

Q. So you did not see his testimony that the 132.7 units could only come from programming basal and/or bolus?

A. I am not aware if his testimony in Brackin Exhibit No. 22 are photographs of the different screens of the -- my understanding

the subject pump.

Q. Okay. Do you know if there is a temporary blocked vent and an overdelivery of insulin related to a temporary blocked vent, do you know if the totals of the insulin delivered would appear on that screen for the total insulin delivered for the day?

A. One more time?

Q. Yeah, it probably wasn't worded real well.

If there's a temporary blocked vent that leads to an overdelivery of insulin, do you know whether or not that information is recorded anyplace on the insulin pump?

A. If there is a temporary block whether it's recorded on the insulin pump; is that what you're asking me?

Q. Yes.

A. I'm not aware of a recording that there was a temporary vent block on the insulin pump.

Q. Okay. So let's start with this, so you're not -- you don't have any evidence or you're not aware that there's any sort of

reporting or recording in the insulin pump in this case that there was an overdelivery of insulin from the temporary blocked vent?

A. It's my understanding the pump does not record that there was a temporary blocked vent event. Blocked vent event.

Q. Okay. And is it also your understanding that the insulin pump would not record any amount of delivery of insulin from a temporary blocked vent?

A. I did not get into that analysis during my investigation.

Q. So given that you didn't go into that analysis, you don't have any awareness in this case that there's a register or number or something in the data from the pump recording a specific amount of overdelivery of insulin from a temporary blocked vent?

A. I don't know and I didn't assess the pump to determine how it was recording the amount of insulin delivery associated with a temporary blocked vent event.

Q. And you mentioned the priming of 3.1 units earlier?

A. I don't recall mentioning that, but it is in my report.

Q. Okay. Does that impact your analysis at all in determining whether there was a temporary blocked vent?

A. I don't believe that it does. It's just part of my understanding of what was occurring.

Q. Okay.

A. Or what did occur.

Q. So the amount of that manual prime of 3.1 units, that doesn't impact your opinion whether or not there was a temporary blocked vent in this case?

A. As to whether it was 3.1 or 3.2 or 3.0, does not.

Q. Okay. And if it was -- the prime was 10, that wouldn't impact your opinion as to whether or not there was a temporary blocked vent?

A. At this point, I don't know.

Q. So the amount of the manual prime has no impact on your analysis of whether or not there's a temporary blocked vent?

A. Yeah, I don't believe I factored in the specific amount of the manual prime in determining my understanding as to whether or not there was a temporary blocked vent at issue or an event that occurred that caused the overdelivery of insulin to Mrs. Brackin on the 14th and 15th of January.

Q. Did you speak at all with Mr. Brackin in coming to your opinions?

A. I did not.

Q. Have you spoken to any treating physicians at all in coming to your opinions?

A. I have not.

Q. Have you spoken to any other family members of the Brackins in coming to your opinions in this case?

A. I did not. I relied upon Mr. Brackin's deposition testimony for the drafting of my report, and I relied upon Luci Brackin's deposition testimony after my report was written.

Q. Do you agree that Mr. Brackin based on his deposition testimony demonstrated an ability to refill the reservoir consistent with

the instructions provided with the getting starting guide, including placing the reservoir over the vial before moving it?

A. I do remember seeing the video of the deposition, I believe, and watching him fill the vial and then remove the vial -- the reservoir from the transfer guard with the correct orientation of the insulin pump vial and reservoir with respect to Medtronic's IFU and Getting Started Guide.

Q. Is there any testimony in this case supporting that Mr. Brackin on the evening of January 14, 2016 incorrectly refilled the reservoir with the orientation of the insulin vial on the bottom?

A. Yeah, I don't recall Mr. Brackin having a specific memory of how he did the actual task on the night of the refill or January 14th.

There's testimony for Mrs. Luci Brackin that the need to have the reservoir over the vial, insulin vial, when removing the reservoir from the transfer guard was not emphasized during the pump training that they

all received when Mrs. Brackin began her insulin pump treatment, and I believe that Mr. Brackin had similar testimony.

Q. Okay. But you haven't seen any testimony from any witness that in fact Mr. Brackin had the orientation reversed where the reservoir was on the bottom and the insulin vial was on top?

A. Yeah, it's my understanding that it was just Mr. Brackin and Pamela Brackin present at the time that the infusion set was changed. And, again, I'm not aware of Mrs. Brackin ever having the opportunity to testify or to provide a statement, and I don't recall anything in Mr. Brackin's testimony regarding his being able to remember what the orientation was at the time or the night prior to the 15th of January.

Q. Okay. So then you haven't -- there's an absence of evidence as to what the orientation was the evening of January 14th, 2016; is that correct?

A. There's an absence of witness testimony as to what actually occurred.

Q. Okay. There's an absence of witness testimony as to what actually occurred on January 14th, 2016 with regard to the orientation of the reservoir and the insulin vial; is that correct?

A. That's my understanding.

Q. And did you review the deposition testimony of Kristin Bettis where she discussed that she would train patients to place the insulin vial on the bottom on a table with the reservoir on top?

A. I don't believe she testified to that specifically.

Q. Okay. Do you recall seeing any testimony from Kristin Bettis about utilizing a table when going through the refilling process of the reservoir and with the insulin vial?

A. My recall is that she would start with the insulin vial on the table, but I do not recall her showing training or demonstrating having either the vial or the reservoir on the table when removing the reservoir from the transfer guard.

Q. Okay. Is your understanding that

there was a temporary blocked vent in this case, is that an assumption you've made?

A. It's my understanding, so it is an assumption.

Q. Is it an assumption that you've tested at all?

A. It's not an opinion, so there was no need for me to test it, it's just my understanding.

Q. So in your analysis of this case, you started with the assumption that there was in fact a temporary blocked vent on January 14th -- 15th 2016?

A. No, I did not.

Q. Okay. Explain that.

A. It's my -- based upon my review of the documents both in the Brackin incident and the Dennert incident that there was a temporary blocked vent -- potential associated with the infusion set and reservoir due to the design of the vents in the manner in which the units were connected and the reservoir was filled with -- with insulin, the hazard associated with that was a laid out fairly clearly in the Medtronic

documents for the potential of over or underdelivery of insulin, which, of course, can create or contribute to catastrophic injuries to the patient. Those exists whether or not Mr. or Mrs. Brackin were ever provided with the subject pump and infusion -- infusion set.

The second part of my analysis regarding the failure to conduct a proper risk and human factors analysis, again, does not involve whether or not Mr. or Mrs. Brackin were ever given the pump. Those failures preexisted Mrs. Brackin's prescription of the pump. They were actions that Medtronic failed to take that they should have taken much before Mrs. Brackin was ever given the pump or the infusion set or the reservoir to use.

Medtronic's failure to provide adequate warnings and instructions also are independent as -- of what Mr. and Mrs. Brackin may or may not have done. Again, those failures preexisted the prescription of the pump and infusion set to Mr. and Mrs. -- or Mrs. Brackin. So that's -- that's what I meant.

Q. Okay.

A. What I mean.

Q. So you -- go ahead.

MR. HAVERTY: Just so we're really clear, his opinions go to the issue of whether or not the product was defective in its design. And that's really essentially what he's talking about, so that's why he says this is independent of what -- what actually happened that night.

He's really just here about defective design and inadequate warning with -- in the face of a hazard that could have been foreseeably that's -- so I just want you to understand what the -- the parameters of his opinions are.

BY MR. MERRELL:

Q. I think, yeah, I'm understanding.

So you -- you -- your analysis in this case of the potential hazard that you just discussed and of the instructions for use in human factors issues surrounding it, you -- that's really irrespective of what actually

occurred in this case in terms of whether there was a temporary blocked vent; is that correct?

A. Whether or not there was a temporary blocked vent that occurred to Mrs. Brackin on the evening of January 14th going into the 15th is not relevant to whether or not Medtronic failed to conduct a proper risk and human factors analysis, whether or not they failed to provide adequate warnings and instructions, and whether or not the product was defective because of their failures.

The only thing that's relevant to with respect to my opinions is the causation, and for that causation opinion, I have to make the assumption based upon my understanding that there was indeed or in fact a blocked vent, temporary blocked vent, a blocked vent event that occurred on January 14th going into the 15th of January.

Q. So the only way you can make the causation opinion you just referenced which is in your report is through an assumption that there actually was a temporary blocked vent, correct?

WILLIAM J. VIGILANTE, JR.

A. Correct. So if there's not a temporary blocked vent, I would not have been able to connect Medtronic's failure to the defect evident product to the actual injury to Mrs. Brackin. So the injury to Mrs. Brackin, my understanding would be there would have to be a temporary blocked vent event to have occurred to link the failures and the defect to the injury.

Q. Okay. And you haven't evaluated other potential sources or causes of an overdelivery of insulin in this case; is that correct?

A. I have not -- well, I take that back.

So, again, it was not part of my analysis to determine whether or not there was a temporary blocked vent event that occurred.

But as I mentioned earlier, based upon my review of the material, I didn't see another potential cause of the overdelivery of insulin, and what I did see was consistent with my understanding and knowledge of these types of events. So I wasn't asked to do the analysis, but in my analysis, I did not find

WILLIAM J. VIGILANTE, JR.

that there was another potential.

Q. Okay. That's helpful. So it was not part of your analysis to determine whether or not there was a temporary blocked vent that actually occurred here?

A. It was my understanding it was an assumption I used to link the causation.

Q. Understood. But it wasn't your analysis to determine whether or not there was a temporary blocked vent that actually occurred?

A. That's correct, I did not set out or was asked to determine that.

Q. Okay. Your -- sort of your bucket is really more into evaluating the hazards we discussed and the human factors issues and instructions for use and labeling issues surrounding it?

A. And design.

Q. And with respect to design, though, I think we already covered this, you're not addressing alternative designs or how the -- the product could have been designed differently; is that correct?

WILLIAM J. VIGILANTE, JR.

A. Again, I have an understanding and assumption that there were other types of alternative designs that were available to eliminate the potential for a blocked vent -- or, excuse me, an over/underdelivery of insulin due to a blocked vent. But I did not do the analysis to show that what those alternative designs were or the feasibility --

Q. Okay.

A. -- of those alternative designs.

Q. So you haven't done any analysis of potential alternative designs or the feasibility of those alternative designs to address this hazard that you've identified; is that correct?

A. I was not asked to do that, and I did not do that, but it's my understanding that there were.

BY MR. MERRELL:

Q. Okay. I'm going object as nonresponsive.

And I take it you -- since you didn't really consider or analyze whether there was a temporary blocked vent or analyze

WILLIAM J. VIGILANTE, JR.

potential causes for overdelivery of insulin, you didn't consider whether or not Mrs. Brackin changed the temporary basal rate, for example, as an alternative?

A. I did not specifically investigate that. I did not see any evidence of it in my review of the file material.

Q. Okay. But you are -- as you're going through this, your analysis per your report, temporary basal rate was not something that was part of your analysis; is that correct?

A. I did not specifically do an investigation to determine that.

Q. And you're not here as a design engineer; you would agree with that?

A. I would be here as a human factors design expert.

Q. You're not offering an opinion that the design of the P-Cap was inappropriate, are you?

MR. HAVERTY: Objection.

THE WITNESS: Yes, I am. Given the risk associated with contaminating the underside of the membrane, it was

WILLIAM J. VIGILANTE, JR.

something that they should have -- Medtronic should have identified during the design and development of the product and then taken steps to eliminate and/or guard against that potential.

It's my understanding that there were feasible alternatives at the time it was designed and first manufactured that eliminated and/or prevented this type of hazard from occurring.

It's my understanding that the standard and the insulin pump industry pre-2000 was -- was called a Luer Lock that did not have vents that did not have the potential to be blocked and lead to a closed -- temporary closed vent or closed blockage -- excuse me, temporary blockage of the vents because there wasn't any vents.

So Medtronic's design to include a waterproof feature of the product, which they never marketed as, introduced a hazard that didn't need to exist, so I would have opinions regarding that topic.

WILLIAM J. VIGILANTE, JR.

BY MR. MERRELL:

Q. I just want to follow up on a couple of things. I asked you earlier about Mr. Brackin and his testimony. And you said you actually saw the video; is that correct?

A. I believe so, yes.

Q. And you agree then -- and that video, was that about two years after the incident?

A. His deposition was March 2018. So we're looking at, I believe, two-plus years if I'm not mistaken.

Q. Okay. And Mr. Brackin two-plus years after the incident at issue, he hadn't done any infusion set or reservoir refills since then, had he?

A. I don't recall him being asked that, so I don't know.

Q. You would agree that there wouldn't really be any reason for him to ever do a reservoir and infusion set change after this date given that his wife passed away; is that correct?

A. I don't -- I didn't look into whether or not he had any reason to, and I don't

WILLIAM J. VIGILANTE, JR.

believe that he was asked that in his deposition.

Q. Okay. In any case, two years after the incident occurred, you agree he was still able to demonstrate the proper sequence of refilling reservoir including having the reservoir on top of the insulin vial before moving it?

A. So I think I need to amend my answer. I don't know that I ever saw the video. I think it was just my understanding based upon the transcript that he was able to demonstrate the procedure consistent with the preferred method of Medtronic during his deposition.

Q. Okay. So you haven't actually watched the video of Mr. Brackin's deposition?

A. I don't have it listed in my material available, and I don't have a specific recollection, so at this point I don't know.

Q. Okay. But based on your review of the reading the deposition transcript of Mr. Brackin, you agree two years after the incident he still demonstrated the ability to correctly refill the reservoir including having

WILLIAM J. VIGILANTE, JR.

the reservoir on top of the insulin vial as the last step before removing it?

A. Yes, it's my understanding during his deposition that he was -- he was able to demonstrate the preferred method of Medtronic with regard to removal of the reservoir from the transfer guard with the reservoir on top of the insulin vial.

Q. And there's -- you agree there's no testimony that Mr. Brackin did not have an appropriate understanding of the steps for refilling the reservoir?

A. I don't recall in his testimony that he was specifically asked that question. Yeah, I don't recall him being specifically asked that question.

Q. Okay. Maybe I didn't ask the question right. I wasn't really asking specifically about his testimony.

You haven't seen any testimony in this case that would indicate that Mr. Brackin did not have an understanding of the appropriate steps of refilling?

A. I don't know that he was ever asked

if he had an understanding of the appropriate steps.

It's my understanding that after they were given the pump and brought it home, he followed the Getting Started Guide for the five or six times he did the insulin pump -- or infusion set change. I don't recall him being asked if during those five or six times he was following the Getting Started Guide, that he understood or appreciated the need and the preference of Medtronic to have the reservoir over the insulin vial when it was removed from the transfer guard or that the insulin vial -- or, excuse me, the reservoir needed to be removed from the transfer guard before the insulin vial. I don't recall him ever being asked those questions.

Q. Okay. Well, my question is a little bit different.

Have you seen any testimony at all to suggest that Mr. Brackin was not following the appropriate steps from the Getting Started Guide?

A. At what point in time?

Q. At any time.

A. Yes.

Q. Okay. Which testimony is that?

A. Testimony that he changed the infusion set on the evening before January 15th which led to the closed -- temporary closed vent event, which is consistent with changing or removing the vial -- or, excuse me, the reservoir with the vial above it. So that would be evidence of him not doing it correctly all the time at the very least.

Q. That's based on your assumption that that actually occurred, correct?

A. That's correct.

Q. Okay.

A. Well, it's my assumption that's what the event was.

Q. Okay. Is an assumption, is that evidence?

MR. HAVERTY: Objection. You're asking him a legal question.

THE WITNESS: Yeah, I mean, you guys are going to have to figure that out at trial. I have my opinions. I have the

basis for them. The assumptions I made to do my investigations, if those things change, you know, that's -- that's beyond me at this point.

BY MR. MERRELL:

Q. Well, I'm just trying to understand your answer, because when I asked you if you are familiar with any testimony to support that Mr. Brackin did not have an appropriate understanding of the refilling, you pointed back to the assumption that there actually was a temporary blocked vent in this case, correct?

A. I don't believe that's the exact question you asked me to be fair. But part of my analysis is the assumption that there was a temporary blocked vent that occurred.

It very well may be that there was another liquid that contaminated the top of that reservoir other than the insulin, but the most likely cause is the fact that the evening of January 14th Mr. Brackin removed the reservoir while under the insulin vial consistent with the known use of the product that preceded that evening and preceded

Mrs. Brackin's being prescribed the pump in the first place.

So this is a known use. Medtronic was well aware of it, and they should have been aware of it when they designed it back in 1999 and 2000. So the testimony evidence that I would point to is the fact that Mr. Brackin changed the vent -- or changed the -- changed the infusion set the evening before Mrs. Brackin was found unresponsive.

Q. So the only testimony you're citing as support that Mr. Brackin refilled the reservoir with the reservoir on the bottom and the vial, insulin vial, on top is his testimony that he changed the infusion set on the evening of January 14th, 2016?

A. Yes and no.

Q. And what is the no?

A. Well, there's other testimony. So, for example, Mark Curtis in his -- in his deposition back in 2005 testified as to how he determined what was going on. The fact of the matter was that Mr. Curtis did the same thing that I'm concluding that Mr. Brackin did during

his investigation as to why this was occurring. He removed the reservoir from the transfer guard with the insulin vial over it, even though, he, as I noted in my report, was well aware of and had been trained and had done it multiple times before that he was supposed to remove the reservoir according to the instructions while above the insulin vial.

So I think there's other testimony, too, that eventually Medtronic employees became aware of why and how these closed vents -- these blocked vent -- blocked vent events were occurring. So that background information as to Medtronic's knowledge, which is also consistent with the discovery material they provided, it's consistent with the -- the emails from their global help or support center that they were aware of it, consistent with the YouTube videos that I pointed to.

So all of that evidence is consistent -- or it shows that the -- the cause of these closed vent is getting material, a liquid or foreign substance, on top of the reservoir before it's connected to the P-Cap,

and that the likely -- most likely cause of that is the end version of the vial in the reservoir while the reservoir is removed. So taking that information and knowledge and applying it to what happened in my understanding of the event that occurred on the 14th and 15th of January, Mr. Brackin's testimony would suggest that that's in fact what occurred more likely than not.

Q. And Mr. Curtis, who you referenced, he's a former employee of Medtronic; is that correct?

A. He was an employee of Medtronic's. I don't know that I know his current state, but he was an employee of Medtronic's.

Q. And Mr. Curtis, he doesn't have any awareness at all -- or what occurred with respect to Mr. Brackin?

MR. HAVERTY: Objection.

THE WITNESS: I have no idea. His deposition testimony was 2015. What he learned after his deposition testimony, I'm not -- I'm not privy to.

BY MR. MERRELL:

Q. Well, if you don't know whether or not Mr. Curtis was aware at all of what happened on January 14, 2016 with respect to Mr. Brackin specifically, wouldn't you agree you wouldn't be able to cite Mr. Curtis's testimony as to actually what happened that night?

MR. HAVERTY: Objection. He already testified to that.

THE WITNESS: No, that's not correct.

BY MR. MERRELL:

Q. So even though Mr. Curtis may or may not have any idea what happened with respect to Mr. Brackin refilling on January 14, 2016, you can somehow rely on his testimony as to what actually did occur?

A. Again, I would use Mr. Curtis's testimony again to build the background and understanding as to why contaminates were getting on top of the -- on top of the reservoir and contaminating the P-Cap when it was connected to it. And that was because the

reservoir was being removed from the transfer guard with the insulin vial over it. So I would rely upon that part of Mr. Curtis's testimony to determine and conclude of what happened to Mr. Brackin on the evening of the January 14th.

Q. Okay. So because Mr. Curtis demonstrates that it is possible to have liquid on the P-Cap resulting in a temporary blocked vent, you're relying on that to show or demonstrate that in fact it did occur with respect to Mr. Brackin on January 14th when he changed the infusion set?

MR. HAVERTY: Objection. Mischaracterizes his testimony.

THE WITNESS: Yeah, so I believe Mr. Curtis came to the conclusion that this is why the closed vent -- vents were occurring, not that it was impossible, but this is why they were occurring.

And, again, he determined how it occurred based upon his -- his testing once -- once Medtronic had received those two videos from Germany back in 2013. So

WILLIAM J. VIGILANTE, JR.

he concluded what the cause was. The cause was the user removing the reservoir under the insulin vial, removing it from the transfer guard, and then having the insulin drip or spill or contaminate the top of the reservoir and then connecting the P-Cap to it.

So that's what he concluded was occurring. Again, his testimony is part of my understanding and background as to what was going on, what Medtronic's understanding of what was going on. And then looking at Mr. Brackin on the evening of January 14th is consistent of the outcome, the closed vent causing the overdelivery of insulin, is consistent with what Mr. Curtis found and what Medtronic was finding, and what was shown in the YouTube videos that I pointed to, what was found in the YouTube videos that Medtronic's global support management team had found back in 2013. So that's how I would use and rely upon Mr. Curtis's testimony.

WILLIAM J. VIGILANTE, JR.

BY MR. MERRELL:

Q. Okay. I'm going to object as nonresponsive.

You would agree that there's not been any testimony from a witness in this case that there was actually liquid on the reservoir P-Cap on the night of January 14, 2016?

A. Again, it's my understanding that Mr. Brackin and Pamela Brackin were the only two present when the infusion set was changed. Mr. Brackin did not testify that he was aware that there was liquid on the reservoir -- or top of the reservoir prior to it being connected to the P-Cap connector.

Q. Okay. And you would agree that Mr. Brackin, he -- he never testified that every had at any time refilling the reservoir the insulin vial on the top with the reservoir on the bottom; would you agree with that?

A. I don't recall him ever testifying to that.

Q. Okay.

A. We've been going about another.

Q. Yes, sure.

WILLIAM J. VIGILANTE, JR.

A. Can we take a break?

THE VIDEOGRAPHER: We're now going off the record. The video time is 12:13 and this ends DVD number two.

- - -

(Whereupon, a short recess was taken.)

- - -

THE VIDEOGRAPHER: We are now back on record. The video time is 12:59 and this begins DVD number three.

BY MR. MERRELL:

Q. Okay. I'm just going to just clean up a few things and backtrack a bit things in my notes.

We talked a little bit earlier about the 2016 and 2000 FDA guidance on human factors. That's something that you referenced in your report, correct?

A. I reference the 2000 version in my report.

Q. Okay. You referenced the 2000 version and you have, I think, the 2016 version on the CD over there?

WILLIAM J. VIGILANTE, JR.

A. Yes.

Q. Is it still your understanding that these FDA guidances from 2000 and 2016 are not actually requirements?

A. I'm not aware of them being regulations.

Q. Okay. So given that they're not regulations, they're not FDA requirements; is that accurate?

MR. HAVERTY: Objection. He said what he thought they were, they're not regulations.

THE WITNESS: Yeah, they're not regulations.

BY MR. MERRELL:

Q. Do you know whether or not they're requirements?

A. Well, I think that if the FDA had a requirement, it would be a regulation.

Q. Okay. So you would think a requirement from the FDA would have to be in the form of a regulation; is that accurate?

A. I believe so.

Q. And these two guidances are not

regulations, correct?
A. The 2000 was not part of a FDA regulation at the time.
Q. Is it part of an FDA regulation now?
A. I don't know.
Q. Do you know if you had all of the human factors evaluations performed by Medtronic for the P-Cap in your assessment?
A. I'm aware of the usability studies that were testified to by Susan McConnell.
Q. Anything else?
A. That's all.
Q. So you haven't reviewed anything other than those usability studies testified to by McConnell?
A. I don't believe so.
Q. Would you agree that if Pamela Brackin did not have a temporary blocked vent, then your opinions would not be causally related to this case?
A. With respect to causation, that's correct.
Q. You also prepared an expert report and a supplemental expert report in the Dennert

case; is that correct?
A. I know I prepared a report. I don't know if I prepared a supplemental report or not.
Q. Okay.
A. Oh, yeah, I do recall. I did -- I did produce at least one supplemental report. There may have actually been two.
Q. Do you recall with your initial report in the Dennert case that you did not have the deposition of Susan McConnell?
A. That was the case.
Q. And in that initial expert report for the Dennert case, did you indicate that there had not been any human factors analysis by Medtronic?
A. Based upon the testimony that I had from Randy Adair and others, did I conclude that.
Q. And then after you reviewed the McConnell deposition, did you supplement it to correct that mistake in your original report?
A. After I received the McConnell deposition, I updated my report.

Q. Other than that one --
A. I'm sorry, I supplemented my report.
Q. Other than the one issue with respect to the McConnell deposition, do you stand by the opinions and information you put in your Dennert reports?
MR. HAVERTY: Objection. Asked and answered.
THE WITNESS: I don't remember everything that was in them, but I don't recall anything specifically offhand I don't agree with.
BY MR. MERRELL:
Q. Do you know if you copied any of the portions of the expert report from Dennert into the Brackin report?
A. I did reuse some of the material.
Q. Do you know if the Brackins ever reviewed the IFU for the reservoir or infusion set?
A. It's my understanding Mr. Brackin testified that they did not, they only relied upon the Getting Started Guide.
Q. And did they, similarly, did they not

review the User Guide for the insulin pump?
A. I'm -- the testimony is they only used the Getting Started Guide, they only used it during training, and that was the only thing they referenced -- that he referenced after -- after training.
Q. Is there any testimony that the Brackins did not understand the Getting Started Guide for the insulin pump?
A. I don't think that there was any testimony that -- from Mr. Brackin that he didn't understand the information in the Getting Started Guide.
Q. Have you ever been involved in a CAPA process?
A. I'm sorry, one more time?
Q. Have you been involved in a CAPA process?
A. I have not.
Q. Have you ever been involved in post-market surveillance program for a medical device?
A. I have not.
Q. Have you reviewed the transcript from

the 24-hour helpline call that Mr. Brackin placed to Medtronic at all?

A. I don't believe so.

Q. So you're not aware of any of the information that Mr. Brackin may have conveyed to the Medtronic 24-hour helpline in his call?

A. The only information I would have is what Mr. Brackin testified to regarding him calling Medtronic when he received the -- I think there was a failure -- error message that came up on the pump the day -- either the day of or the day after the event.

Q. So the only information -- sorry.

A. I can't -- motor error I think was the message that appeared on the pump screen.

Q. So the --

A. He called -- he called Medtronic's helpline to speak -- to speak to -- and spoke with a representative about the motor error message.

Q. So the only information you have regarding that phone call that Mr. Brackin placed is from his testimony and exhibits from his deposition?

A. I believe so.

Q. Have you been involved at all in any trending analysis of complaints for a medical device manufacturer?

A. I have not.

Q. And have you ever been involved in assessment or analysis of whether or not there was a signal from trend analysis for a medical device?

A. For on behalf of a --

Q. No.

A. -- medical device?

Q. Not limited to that.

A. I don't believe so.

Q. Did you conduct any sort of assessment or analysis in this case of the complaints coming into Medtronic to assess whether there was any sort of signal to Medtronic regarding a temporary blocked vent, for example?

A. I did look at the testimony and the exhibits and the data that came in. Over the years, Medtronic has tracked this in different ways using different error codes. And based

upon the error code that were used, they were coming to different figures, if you will. So I believe that at one point they were looking at identifying a handful of potential temporary blocked vent events.

They then -- when they looked -- relooked at the error codes, they moved that up -- that estimate up until about 90 events a year, and then when they moved to the -- I think it's EO or EA30 or 35 code in between 2013 and 2014, after the health care -- Dear Health Care letter, I think they determined that there were on the order of 750 reported events.

So I think that's my understanding of the -- at least the history of the recording and reporting of these types of events.

Q. Did you try to make any sort of analysis as to the -- the occurrence level, whether it's extremely rare, rare or common in terms of a temporary blocked vent?

A. I didn't do an in-depth investigation of it. What I did note is in one of the -- one

of the emails, if I remember correctly, that were discussing at the time the prime fill anomaly, which they were calling it prior to the temporary blocked vent event, they had noted there was something in the order of -- I can't remember the numbers, but they gave the numbers and then they gave what they thought was a number of reported events based upon the old error code. I think that's the only statistic I've seen in my review of all of the discovery documents and deposition testimony I've looked at.

Q. Do you remember what that statistic was, was it a percentage?

A. They didn't provide a percentage; they just provided the two numbers. And, of course, if you have the two numbers, you can do the percentage.

Q. But you haven't taken an analysis of what the percentage was of prime -- prime fill anomaly events or temporary blocked vents that came into Medtronic?

A. I don't know that I specifically did the calculation, but it was something on the

order of less than 1 percent. That's assuming that there were only 90 events reported that year.

But, again, they changed the error classification or the classification of the event, and they went from 90 a year to 750 a year, so that, of course, would change the percentage. But they didn't provide the -- I didn't see any data of them providing the number of infusion or -- or pump patients.

And I don't recall if the number that I did see was pump patients or the number of infusion sets sold in the year. So that would be a different analysis depending upon whether you're looking at patient population or the number of infusion sets sold.

Q. So I take it sitting here now you don't have a percentage in your mind of what percentage of prime fill anomaly events or complaints that came in compared to the total number of infusion sets?

A. Yeah, I don't know what the exact number is. I do know that more than one was one too many, but I don't know what the exact

number is.

Q. Is it your view then that one incident of temporary blocked vent or prime fill anomaly should have initiated action by Medtronic?

A. It's my view that they should have identified this before they put this product on the market. And had they, they wouldn't have had one reported incident, and they wouldn't have had one injury or death because of it.

Q. Uh-hum.

A. This was a foreseeable consequence of the design of that vent system on the top of the P-Cap, and it's something through proper human factors and risk analysis that a prudent manufacturer of Medtronic's -- Medtronic's place would have and should have caught --

Q. And --

A. -- and addressed.

Q. So you -- your opinion is that somewhere in the 2000 time frame Medtronic should have identified this hazard?

A. It should have been identified during development.

Q. And I take it then you disagree with Mr. Klimowicz that it would have been difficult to identify a temporary blocked vent as a potential hazard?

A. I don't know what Mr. Klimowicz testified to regarding that topic. But it's my opinion that through proper risk and -- excuse me, risk and human factors analysis, this would have been identified during development.

Q. So would you disagree that it would have been difficult to identify temporary blocked vent as a potential hazard during development?

A. Given the way they designed the product, I would. They didn't have any human factors input into the design until they were looking at the usability, quote/unquote, usability testing of the IFU. At that point you're integrating human factors late into the design process. It should have been up front.

As I note in my report, part of the risk assessment should have included a task analysis. And based upon Randy Adair's knowledge regarding what can happen when the

vents were blocked and there was not equalization of the pressure inside the vial and the atmosphere outside, this should have been caught during development had they integrated and conducted proper risk and human factors analysis.

Q. Would you agree that if the instructions for use in the Medtronic Getting Started Guide are followed, you would not have a temporary blocked vent occurring?

A. Yeah, I don't know that that's the case. And certainly, it depends upon which tradition of the IFU.

So if you follow the instructions in the 2000 -- the IFU that was provided with the infusion -- the reservoirs in 2013, 2014, in the -- I have to go back and look at the pump manual. But if you follow those two versions of the IFU, your chances of getting insulin squirting onto the reservoir and removing the reservoir from the transfer guard were minimized.

But there was still a risk of getting liquid either on the P-Cap or the top

of the reservoir from other sources while doing the infusion set changeover. So it's not just the insulin that could potentially lead to the closed block, it could be any -- any other type of liquid or oil. So it was still possible even if you follow with those IFUs to have the event occur.

Q. And so I just want to narrow this a bit. Would you agree that if you follow the instructions for use specifically in the 523 insulin pump that the Brackins were provided and relied upon, if they follow the instructions for refilling the reservoir, would you agree that you could not have a temporary blocked vent?

MR. HAVERTY: Which instructions?

BY MR. MERRELL:

Q. Oh, I'm sorry, I'll ask it again if it's not clear.

MR. HAVERTY: No, no, because there are several sources for instructions.

BY MR. MERRELL:

Q. No, I understand. I thought I was being specific, but I'm going to try it again.

Would you agree that if the Brackins followed the -- well, I'll tell you what, I'll wait until we get to the Getting Started Guide and it may be easier to do it then.

A. Okay.

Q. Is it your opinion that Medtronic failed to follow the FDA guidances from 2000 on human factors with respect to the -- the infusion set?

A. With respect to the design of the infusion set system, I'm not aware of them conducting any human factors testing or evaluation or analysis. It's not until the usability studies, quote/unquote, were conducted on the IFUs after the product was designed and developed did they implement any type of human factors or usability analysis or evaluation.

Q. Do you believe that those usability studies they did on the IFU complied with the

FDA guidance from 2000 on human factors?

A. Yes and no.

Q. And how did they not comply?

A. Well, they were improperly conducted for what they were supposed to be. So conducting the usability studies in and of themselves is a good thing, but the way in which they were conducted, specifically the user population and the fact that they never evaluated the final IFU to validate it, were improper usability methodologies.

So they -- it was a good thing that they did the testing, but it was a bad thing that they did it improperly.

Q. And is there anything specifically that you cite to in the 2000 guidance as a source for how they should have conducted the usability studies?

A. I don't believe I looked or relied upon the 2000 guidelines specifically on how to do the usability studies.

I'm relying upon my education, experience and training. If you're going to do usability studies with a product that's going

to be used by a known population, it's appropriate to bring members of that population in to rely upon folks that worked for a company that are aware and -- of -- of the products and had experience with them as opposed to first-time users, that's -- and then try to extrapolate those results to first-time users, it's not proper.

So if they were going to do usability studies, they should have brought people in that were potential patients to determine how they responded to the IFUs. And then finally, if you're going to change the IFU based upon your -- your testing, you need to validate it. There was no a validation. There's not even a mention of what was changed from the last time they ran the, quote/unquote, usability study on the IFU.

And, again, doing the usability study on the IFU is putting the cart after the horse. Human factors analysis should have been done during the design of that system.

The task analysis should have been done before they actually put the parts

together. When prototypes were available, they should have had users coming in to see how they would interact with them way before the IFU is even developed. So, again, that's another part of the usability studies, quote/unquote, that was improper.

Q. Would you agree that the 2000 FDA guidance does not say anything about having to use first-time users for the usability study?

A. I don't recall whether or not it does. I'd have to read through the entire document.

But proper usability testing methodology includes using people representative of the user population. If you're going to do other forms of human factors evaluation such as hallway testing, then it's appropriate to use a convenient sample such as fellow employees or coworkers. But to do usability testing, it needs to be done within users; otherwise, it's not providing you valid -- valid results for its intended purpose.

Q. Is there a specific reference in your

references on page 25 of your report that you rely upon regarding that issue?

A. I don't know if there is or there is not. But I can tell you based upon my education, experience and training what the proper way to do a usability study is, and it was not done by Medtronic.

As I mentioned a little bit earlier, using coworkers or a convenient sample is appropriate for early hallway testing. But the purpose of the usability study is to bring actual end users in to see how they use the product, and that's not what Medtronic did.

Q. Is there a specific human factors guidance or literature that you're citing for that point?

A. I don't have a specific example offhand. I'm again relying upon my education, experience and training that includes specific guidances, but I don't -- didn't think it was necessary to cite one in this case.

The whole purpose of usability studies is to bring the user in. If you're not going to bring the user in, you're going to use

somebody who's not the user. It's not a usability study. It's a fairly simple and basic principle. So I apologize, I didn't think to bring in a specific reference to support it.

MR. MERRELL: I'm going to mark as Exhibit 6 the Getting Started Guide that was produced at Brackin's deposition as Brackin-23.

- - -

(Whereupon, Exhibit 6 was marked for identification.)

- - -

THE WITNESS: So to update my prior response, the 2016 FDA human factors of medical device does note under actual use testing that, quote, in such a test the test participants should be representative of the actual users, the clinical environment should be representative of the actual use environments, and the testing process should affect the participant's interaction with the device as little as

possible.

So that would be one reference to support my opinions regarding whether or not using coworkers and not the end user population as appropriate.

BY MR. MERRELL:

Q. Okay.

A. So, and then on page 21, when they talk about test participants, under section eight human factors validation testing, it notes, quote, the most important consideration for test participants in human factors validation test something that they represent the population of intended users. So I just wanted to clarify that and append that answer.

And, I'm sorry, what was your next question?

Q. That's okay. Well, I'll follow up on that actually.

There was not a question pending, I was just giving you that.

You cited that the 2016 FDA guidance on human factors with respect to requiring that you use actual -- or the

participants be actual users. You do understand that that -- that came out well after the products were developed here?

A. Two things: One, it says that you use people from user population. They don't have to actually be users. So, for example, when you're developing new product, you're not going to have users because the product is not in existence. So you want to bring people in from the user population. Number two, that document is from 2016, but, again, it's just repeating a basic principle of human factors evaluation in usability testing.

I can tell you when I was conducting usability testing for the IBM Corporation on products that was designed for both consumer and commercial purposes, if they were not representative of the user population, it was not a usability test. It would fall under the category of hallway testing, convenient sampling testing. Usability testing infers that you're bringing in people from the user population, representatives from the user population.

Q. Okay. In any case, though, the -- this citation you make that the usability study should be done on -- in user populations, that was from the 2016 human factors FDA guidance, correct?

A. The stuff I quoted was from the 2016 guide. As I mentioned, it is consistent with usability and human factors principle going back decades.

Q. Okay. I'm going to object after guide as nonresponsive.

Okay. I handed you a copy of what marked as Exhibit 6. It's the Getting Started Guide. This is the same Getting Started Guide that was produced at Mr. Brackin's deposition as Brackin-23.

I know you reviewed this and this is a source for your opinions, correct?

A. I had a copy of the Getting Started Guide that the Brackins had and marked up during their training.

I should append that, too. It wasn't just the Brackins who marked it up, it was also the certified trainer, Ms. Bettis.

Q. Okay. If you turn to page 57.

A. Sure. Okay.

Q. Page 57, the title is changing the quick set infusion using a Revel Insulin Pump; do you see that?

A. Yes.

Q. And does this provide the instructions for changing the infusion set as well as refilling the reservoir?

A. Yes. It starts with rewinding the piston in the pump and then filling the reservoir and connecting the reservoir to the infusion set and then it's going to get to inserting the infusion set into the -- the quick set attached to the body.

Q. Do you note that at the top of this version, which the Brackins had, it's highlighted at the top, changing the quick set -- infusion set using Revel Insulin Pump?

A. Yes.

Q. Did you see in the deposition of Kristin Bettis that she wanted to emphasize this for the Brackins?

A. That's what she testified to.

Q. If you look at step eight of the Getting Started Guide, does it instruct the user to flip the vial over so it is now on the bottom?

A. It states flip file over so it is now on bottom.

Q. And is it directing the patient to have the insulin vial on the bottom and the reservoir on top?

A. That's the intent of it.

Q. Would you agree with me that if a patient follows the instructions provided here on page 57 through 58 of the Getting Started Guide for the 523 insulin pump, that you would not have a temporary blocked vent?

A. No.

Q. And why is that?

A. Because the contaminate can be something other than the insulin from the insulin vial that could be on the -- that can get on top of the reservoir. And then when the reservoir is connected to the P-Cap, part of the infusion tubing, you have the same effect.

Q. Would you agree with me that if a

user follows the instructions provided here on page 57 to 58 of the Getting Started Guide for the insulin pump, that they would not have a temporary blocked vent from insulin being on the P-Cap?

A. I don't know that they can say that either. I'm sorry, that was my answer, I don't know that you can say that either.

Q. What other source would there be for insulin causing a temporary blocked vent other than -- well, strike that. Let me ask it a different way.

What other possibility would there be from a temporary blocked vent from insulin if the procedure is followed?

A. It could be that you have some insulin that migrates out of the -- out of the reservoir when you are handling it. It could be that you remove the transfer guard from the insulin, or when you put the insulin vial down, some of it gets on your hands and that you then touch the top of the -- of the reservoir.

So I can't say that it eliminates the possibility of insulin

contaminating the top of the reservoir. I think that if you follow the instructions, it minimizes the risk, but it doesn't eliminate it.

Q. You would agree that if you follow the instructions here in the Getting Started Guide from page 57 to 58, that it would minimize the risk of having a temporary blocked vent?

A. The risk of insulin causing the temporary blocked vent event would be minimized if you follow the instructions at the time that you were doing it.

Q. Are you aware of any incidents of a temporary blocked vent where a user followed the instructions provided by Medtronic in the Getting Started Guide?

A. Yeah, I don't know that that data is captured, so offhand, I don't know. And what I mean is not captured by Medtronic.

Q. With respect to the Getting Started Guide specifically, what are your criticisms with respect to the instructions provided on the refilling process?

A. Well, there's two. One is that it's kind of a broader issue that's related to the Getting Started Guide as well as the IFUs and the pump manual. Your -- Medtronic is relying upon warnings and instructions to mitigate a hazard that should have been fixed in the design of the product. So what happens is, is although a user such as Mr. Brackin, who follows the guide for the first five or six times, goes to training with the certified trainer and is told and learns to do the task correctly, it doesn't guarantee that at some point in the future they may have lapsed or slipped and do it with a vial below the insulin -- or the reservoir below the insulin vial.

So, for example, Mr. Curtis again testified that he was trained, aware and experienced in doing this process, but yet in his own testing to try to figure out what was causing the prime fill anomaly, as it was known at the time, did exactly that. He had a slip. He put -- he removed the reservoir from the transfer guard below -- from below the insulin

vial. In fact, he testified that because he was using the green solution, that when he saw the -- the green drops on the top of the reservoir, he couldn't at first understand how it got there. He had to stop and think about what he did to cause it to get there, and then he realized that even though he had known how do it appropriately or the way Medtronic intended or -- or -- or preferred it to be done, that he did it the opposite way.

So that's the number one criticisms, is that you're relying upon something that is imperfect, and it's not as reliable as eliminating it through design to address a problem that could have been and should have been addressed through design.

The second part that I have more specifically with the Getting Started Guide is that step number eight is not -- there's nothing to emphasize it. So Mr. Brackin and his daughter testified that when they went through training, the fact that the reservoir needed to be on the -- above the insulin vial when removed was not emphasized. There's

nothing in the Getting Started Guide that emphasizes the need to do that. There's no warning at that point in the task to alert the user of the need to do it and the consequences of failing to do it and so forth. So they're -- they're kind of the specific criticisms I have of the Getting Started Guide.

Q. Okay. So one is essentially they should have designed around it?

A. Absolutely, that's the -- that's the very first problem with -- with relying upon whether it's the Getting Started Guide or the User Guide or the IFUs. You can tell somebody to do it and people are training these things out every two or three days for years, and it takes just one slip, one intention, one hurrying, one distraction, one fatigue, and they don't invert the unit when they remove the insulin -- or the reservoir from the transfer guard, and then they're at risk for a catastrophic injury.

You cannot leave the potential for catastrophic injury at that type of -- at that type of risk. You cannot expect or rely

upon the user to be a hundred percent perfect a hundred percent of the time. It's impossible for a user to be a hundred percent perfect a hundred percent of the time. So you would never want to rely on an instruction or a warning when you're going to address a risk particularly with catastrophic consequences when there was a design solution.

Q. And as I understand it, you're not providing opinions or analysis as to what the solution should be or alternative design; is that correct?

A. I do have opinions on that. Number one, they -- they put in the market, they -- Medtronic introduced this P-Cap so that they can market it as being waterproof. They introduced it into the market, and introducing it into the market introduced this hazard that didn't exist before.

And then they never market it as waterproof, so the very reason that they put it out they never actually market it for that reason. It was improper just to introduce a product with a risk -- a risk such --

catastrophic risk with no utility. So from a risk benefit utility ratio, you got a tremendous risk with no benefit. That's absolutely improper. So that's number one.

Number two is it's my understanding that there were different membranes that could be used. In fact, Medtronic had come up with them, but were delayed in putting them into the -- into the market in 2015, 2016, 2017. Again, they shouldn't have waited 14, 15, 16 years after this product is introduced to getting around to changing the membrane.

So they should have looked -- if they were intending on keeping this product in the market, they should have addressed and looked at the membrane back in 1999/2000. So that's my opinions on that topic.

Q. And you agree, though, the opinions on the membrane or material, that's not in your expert report?

A. It is not.

Q. And opinions on alternative design, that's not in your expert report, correct?

A. I do mention the Luer Lock that did not have the hazard in my report. I do note that they never considered alternative materials --

Q. Okay.

A. -- and alternative designs in my report.

I do note that warnings are means of delegating responsibility for product safety to the users in situations where hazards cannot be designed on or so regarded. And I think that's the only areas I address it -- oh, I do address it one more time at the top of section E4 and -- or I note that Medtronic -- if Medtronic choose not to design up a hazard, it should have at least provided adequate instructions and warnings with the infusion set and reservoir.

Q. But you don't state in your report specific opinion that a specific design should have been implemented?

A. I don't provide a specific design other than mentioning the Luer Lock did not have that hazard.

Q. Okay. You mentioned that, but you don't -- you don't provide an opinion that they should done a specific design as an alternative?

A. Oh, no, I don't. I opined that they should have done the proper risk and human factors analysis and identify the risk and then addressed it appropriately.

Q. How should the Getting Started Guide have emphasized the -- the inversion of the insulin vial and the reservoir?

A. I noted in my report with the use of arrows to emphasize the flip. This is also consistent with Medtronic's management team's assessment regarding their IFUs that were used back in the 2013 time frame.

So on page 22 of my report, I provide those examples. In conjunction with the additional pictograph and arrows, I note that a warning should have been provided consistent with the ANSI C535.6 standard to draw attention to the hazard and how to avoid it and the consequences of not avoiding it.

Q. And what would the warning have said?

A. It's noted on page 23 of my report. I'm happy to read it.

Q. Sure.

A. It would start with a signal ward of warning with a signal ward header. It would state something on the order of ensure reservoir top and tubing connector were clean and dry. Liquid can block the vents on a tubing connector causing under or overinsulinization delivery, under or overdelivery of insulinization can result in severe injury or death. If the connector gets wet, throw infusion set and reservoir away and use new ones.

I also note -- so pages 22 and 23 of my report provide the alternatives.

Q. Do you know whether or not there are any other components of the Getting Started Guide and instructions provided that similarly if not followed could have a potential risk of overdelivery of insulin?

A. I imagine that there are other parts if not -- if the pump is not used correctly that can result in over or under -- over or

underdelivery of insulin.

Q. Do you think that in every instance in the Getting Started Guide if there's a potential -- if the instruction is not followed there's a potential for over or underdelivery of insulin, that it should be noted with a warning?

A. Any hazard associated with the use or foreseeable misuse of the product should be noted with a warning if it's not addressed through a design and/or guarding in the manual.

Q. So, hypothetically, if there were 50 instructions in the Getting Started Guide which if not followed could lead to an overdelivery or underdelivery of insulin, should it have a warning that states that?

A. I'd have to look at the specific instances. But generally, the user has a right to know that if a specific step, if not done in the manner which was prescribed in the User Guide, can result in significant injury or death, they have a right to know when you do that through a warning.

Warnings are designed and

formatted to draw attention, or capture attention, communicate the fact that there is safety information, that there's a safety issue associated with that particular step or task as laid out in the User Guide or Getting Started Guide.

Q. And I take it you haven't done an analysis as to whether or not a warning for overdelivery or underdelivery of insulin should be included for any other component of the Getting Started Guide?

A. Yeah, I did not do an assessment of the entire Getting Started Guide to determine what risks or hazards were with different aspects of the -- of the system and/or use of the system.

Q. One of the parts of your task analysis relates to the dominant hand in evaluating the appropriate instructions for use; is that correct?

A. It does. I'm sorry, go ahead.

Q. How would you -- should the User Guide have differing instructions depending if someone is left or right-handed?

A. I don't believe so.
Q. With respect to the 2014 reservoir guide, you have your opinions on page 14 through 15; do you see that?
A. Yes.
Q. And are those criticisms entirely based on human factors principles of which hand to place the reservoir in?
A. In part.
Q. And what else is it based upon?
A. Well, it's noted above that, starting on page 12 and going from page 12 going into 13.
Q. Do you believe there should have been any additional warnings on the 2014 reservoir IFU?
A. Again, they needed -- Medtronic needed to highlight the inversion or the flipping on the IFUs, and they needed to put a warning at the point where you're going to attach the P-Cap to the top of the reservoir.
Q. And the infusion set IFU post-2014, did that need to have a warning as well?
A. Same.

Q. Would you agree that for any product that's developed that there can be unanticipated risks and hazards that are discovered following the marketing of the product?
A. Sure.
Q. And would you agree that a risk analysis of any product is not going to be able to identify every possible risk or hazard of a product?
A. Sure.
Q. Have you ever had any of your opinions excluded in court before?
A. Sure.
Q. How many times do you think?
A. I'm aware of three times I was not allowed to provide testimony at trial.
Q. And have there been times when your testimony has been not excluded, but has been limited by a judge?
A. Sure.
Q. About how many times do you think that's happened?
A. I'm aware of two occasions.

Q. Have you ever rendered an opinion in a case that the instructions and warnings provided were adequate?
A. Yes.
Q. How many times have you done that?
A. I don't know.
Q. Over -- since working with Forensic Consulting -- strike that.
Since 2015, with your own company, have you issued any opinions that warnings or instructions for use were adequate?
A. I believe so.
Q. How many times have you done that?
A. I don't know.
Q. How many cases do you think you've taken since you started your company in 2015?
A. I don't have a number.
Q. Do you have an estimate about how many cases you work on as an expert a year?
A. I'd say 30 maybe.
Q. In the past year, have you issued any opinions that the warnings are --
A. It's probably -- yeah, I'm sorry, it's probably higher than that because I get --

you know, cases tend to back up, so I might have a -- you know, write a report in 2016 and then be deposed in 2018 and go to trial or be deposed in 2017 and go to trial in 2018, so I may be working on a case on different parts over a span of three or four or five years. So it's probably higher than that.
Q. Okay. So the number of cases is probably higher than 30?
A. That I work on in a year, yes.
Q. Did you look at the checklist at all that Ms. Bettis covered with the Brackins as part of her training?
A. You're going to have to show it to me and --
MR. MERRELL: I will. That's fine.
I'm going to mark as Exhibit 7 the Pre-Pump Training Checklist and I'll mark as Exhibit 8 the Pump Start Training Checklist.
- - -
(Whereupon, Exhibit 7 and Exhibit 8 were marked for

WILLIAM J. VIGILANTE, JR.

identification.)

- - -

BY MR. MERRELL:

Q. I'll hand this to you, and I have a copy for you.

MR. HAVERTY: Okay.

BY MR. MERRELL:

Q. And looking at Exhibit 7 and 8, have you reviewed these documents before?

A. Offhand, I don't know. I'm sorry, I answered only to No. 7. I haven't looked at No. 8.

Q. Oh, that's fine. Okay. So we'll just clarify for the record.

A. So these two --

Q. Offhand, you don't know if you reviewed Exhibit 7, which is the Pre-Pump Training Checklist?

A. Did you give me two copies of it?

Q. They look very, very similar. Hopefully, I marked them differently.

A. One is marked, one is not.

Did you give me two pre-pumps?

Q. Maybe. I did. All right. Sorry.

WILLIAM J. VIGILANTE, JR.

Let's fix this.

Oh, I see now, I gave you two of those.

A. Sorry.

Q. So Exhibit 7 is the pre-pump and Exhibit 8, which I gave you previously, is the Pump Training Checklist.

A. So looking at Exhibit 7, I don't recall if I've seen it before.

Q. And what about Exhibit 8, the Pump Training Checklist, have you seen this one before?

A. I don't recall if I've seen this one before either.

Q. Okay. If you look at Exhibit 8, the Pump Training Checklist, is one of the items that's checked there, the second from last, the infusion set patient demonstrated the ability to fill reservoir and change infusion set with minimal assistance?

A. Are you asking me if that's checked?

Q. Yeah, if that's what it says and if it's checked?

A. Yes, that's what -- it's checked. I

WILLIAM J. VIGILANTE, JR.

didn't follow to make sure that's exactly what it says, but something of that nature.

Q. Okay. And this is dated, if you look on the second page, it's dated August 27, 2013?

A. Yes.

Q. And on that day, did Ms. Bettis, did she spend about three hours with the Brackins training them?

A. It appears that way.

Q. Did you read the portion of her deposition of Ms. Bettis?

A. I did read Mrs. Bettis's testimony.

Q. I was trying to ask a question, and I needed water, I hadn't quite finished, my apologies.

Did you read the portion of Ms. Bettis's testimony where she said she spent a significant amount of the time in the training addressing the infusion set change and refilling the reservoir?

A. I do recall that that topic was addressed in her deposition.

You guys want to take five minutes?

WILLIAM J. VIGILANTE, JR.

Q. Yeah, sure.

A. Because I've been sitting about an hour.

THE VIDEOGRAPHER: We are now going off record. This ends DVD number three. The video time is 1:57.

- - -

(Whereupon, a short recess was taken.)

- - -

THE VIDEOGRAPHER: We are now back on record. This begins DVD number four and the video time is 2:09.

BY MR. MERRELL:

Q. Are there particular Medtronic employees that you're critical of in this case?

A. What do you mean?

Q. I don't know. Do you have any criticisms of a specific Medtronic employee in this case?

A. In what way? I don't think any of them are bad people, so I don't -- I'm not sure what you're asking me.

Q. Okay. Would you agree Medtronic is a

good company?

MR. HAVERTY: Objection.

THE WITNESS: I don't have an opinion on them. Obviously, I'm not aware of -- maybe it's not obvious. But I am not aware of all the different products they sell.

BY MR. MERRELL:

Q. Okay.

A. Or different industries they're in. I'm aware of this particular product in this particular system.

Q. Do you have any criticisms of any specific action that a Medtronic employee took in this case?

A. Well, for example, Randy Adair, when he was designing the P-Cap, and I do note in my report that he failed to conduct any type of risk or hazard analysis with the design, and that's improper. He was the guy responsible for designing that thing, but yet he designed it in a vacuum with absolutely no consideration for how it would be used and the environments in which it would be used with respect to its

connection to the reservoir and so forth.

Q. Do you have any other specific criticisms of any Medtronic employees?

A. Not offhand.

Q. Let me ask you a couple more questions about your CV. The front of your CV, you have a title page called human factors and ergonomics experience; do you see that?

A. Yes.

Q. What is the purpose of this particular page of the CV?

A. I put it together back in 2003 when I joined Robson Forensic or a -- a version of it back then just to kind give an overview of the different areas in which I apply my expertise in human factors and ergonomics. And then some --

Q. I'm sorry, go ahead.

A. Well, I'm sorry. Some of it is also a summary of some of my experience in different areas of the human factors and ergonomics as applied.

Q. And one of the areas you have listed here is warnings; do you see that?

A. Yes.

Q. And you have another bullet for vision and driving?

A. Yes.

Q. Another bullet for motorcycle?

A. Yes.

Q. Do you have particular expertise with respect to motorcycle human factors issues?

A. Yes, I have investigated human factors associated with the performance of motorcycle riders.

Q. And do you have significant experience with respect to human factors and ergonomics issues related to vision and driving?

A. Yes.

Q. What about slip, trips and falls, is that an area you have significant human factors experience in?

A. Yes, it was going back to undergraduate and graduate school studying human gait and pedestrian safety whether it be in a work space, work setting, or residential or retail.

Q. What about --

A. Public setting.

Q. You also list workplace safety as a bullet here?

A. Yes.

Q. And you list recreational and sporting activities as a bullet?

A. Yes.

Q. You list lighting as a bullet?

A. Yes.

Q. And do you have accessibility on here as a bullet?

A. Yes.

Q. And then, aging, is that another area where you list here in a bullet?

A. Yes.

Q. And then you list medication labeling as a bullet, too; is that correct?

A. Yes.

Q. And then you have product design and development as a bullet?

A. Yes.

Q. And you have user center design as a bullet; is that correct?

A. Yes.

Q. Do you agree with me that on this page of your human factors and ergonomics experience you don't specific list medical devices?

A. I don't specifically use that phrase "medical devices".

Q. With respect to the medication labeling bullet, what -- what experience specifically are you calling out here?

A. So from, I guess, like the mid-90s until 2004/2005 time frame, I was involved in research -- researching factors that affect the adequacy of medication labeling for both prescription -- excuse me, nonprescription labeling and prescription medication advertising. So that would be what I'm referring to --

Q. Okay.

A. -- with that statement.

Q. So the reference here, the bullet for medication labeling, this is in the 2004 and 2005 time frame -- I apologize, I was misreading that. I'll rephrase it.

The medication labeling bullet you have here is from the mid-1990s to the 2004 and 2005 time frame?

A. That's when I was doing approximately -- I guess it's probably more closer to '95 to about 2004/2005. I was active in research related to medication -- over-the-counter medication labeling and prescription medication advertising.

Q. And what were the -- were there specific aspects of the labeling that you worked on?

A. Yes. So back in the mid to late '90s under grants from the Drug Information Association and in cooperation with the FDA, our lab, generally and myself specifically conducted a number of research studies the factors that affect the adequacy of over -- over-the-counter medication labeling for both adults and older adults. Older adults were specific population of interest. We looked at things as to how to present information on the labels, how to order the information, the effect of font size, information gathering,

effect of light spacing, and other formatting features.

The work that was done and published was used by the FDA when they promulgated their over-the-counter medication labeling regulations in 1999. So a lot of that regulation -- of lot of those regulations were a direct result of the findings from both my research specifically and our lab's research more generally.

Once that project was done or those -- those series of projects were done, I personally went back to my contacts at the FDA to inquire as to what other areas they foresaw the need for human factors-type research. And -- and the big area that they identified was the advertising of prescription medications, which shortly before the late 1990s the government changed their laws allowing pharmaceutical -- pharmaceutical companies more -- giving them more ability to advertise directly to consumers whether it be television, magazines, newspapers or on the World Wide Web.

So both, again, myself specifically and the lab generally conducted another series of projects looking at how to present both benefit and risk information and prescription medication advertisements. Again, our research was fed back into the FDA to help them update and improve the regulations to ensure that consumers were getting a fair balance between the risks associated with a particular medication to the benefits that the medication offered.

Q. Did you do any work in terms of the language of warnings with respect to the medication guide -- or the medication labeling?

A. I don't remember doing anything specifically with specific language in that time frame.

Q. Did you ever write the labeling or warnings for a medication?

A. I did create different medication labels for multiple different studies that were conducted. Is that what you're asking me, or are you asking me --

Q. Describe that for me. The medication

label for the studies, was it for the study or for the actual final labeling of the drug?

A. Well, no. So during the studies, some of the usability studies using actual representatives from the user population, we mocked up containers of over-the-counter medications and mocked up the labels for those containers and then used those labels and containers in the actual studies.

The work that we were doing was not specific for a single drug or a single manufacturer, it was for the regulations. So when you go into the over-the-counter medication labeling regulations and they state, there's a minimum font size, a certain type of formatting, the need for bordering and categorization of the information, the need for ordering the information in a certain order on the label, those requirements are based upon the research findings in part from my work and the work done as others in our lab. So it wasn't for a specific manufacturer or specific drug, it was for regulations in general.

Q. Were these medication labels that

you -- that you mocked up, were these for an actual drug or was it a placebo? I'm just trying to understand.

A. Yeah, we used -- we didn't take, like, for example, in my doctoral thesis or doctoral dissertation, when I was dealing with prescription medication advertisements, I used actual drugs and the information from those drugs and manipulated how it was presented. For the over-the-counter stuff, I think we used the labeling information; so, for example, the ingredients, the directions for use, the warnings and side effects from an existing medication or medications, but changed the name of them so we wouldn't put out a brand name like Tylenol.

You know, we would create a fictitious name, but use the information from, you know, an existing medication or label to create our labels.

Q. Let's take a look at back to your CV. The workshops and continuing education.

A. Okay.

Q. Do any of the workshops and

continuing education you list here relate to medical devices?

A. They do.

Q. Which ones?

A. So, for example, risk assessment in human reliability, some practical tools for improving safety and human factors approach to accident analysis and prevention, there were workshops that covered basic -- or different human factors and risk assessment principles and how to apply them to different -- different systems.

Q. Were medical devices specifically addressed at that workshop?

A. I don't recall them specifically addressing medical devices during the workshops.

Q. Can you recall medical devices being addressed at any of the workshops that are listed here?

A. I don't think the other workshops would be relevant to design medical devices.

Q. Taking a look at your certifications, you have an IPAF operator training

certification?

A. Yes.

Q. What is that?

A. That's the International Powered Access Federation. So it's training for crane operation -- or, sorry, lift operation.

Q. Then you have the Raymond Safety on the Move forklift certification?

A. Yes.

Q. What is that?

A. Again, it's certification for forklift operation.

Q. Then you have a fire con safety emergency response training as well?

A. Yes.

Q. And what is that?

A. That was safety training for confined space entry.

Q. And then you have Motorcycle Safety Foundation, a basic rider course and off-highway motorcycle course?

A. Yes.

Q. What is that exactly?

A. There are two different courses that

are offered by the Motorcycle Safety Foundation. One was for basic rider courses, essentially for street riding. The other one was for off-road motorcycle riding. So there's safety courses for those two different activities.

Q. Do you ride motorcycles?

A. I do.

Q. That's the most important question of the deposition.

Did you take these courses primarily for your own interest or is it also part of your professional experience?

A. Both.

Q. And you have a bullet here for National Rifle Association instructor certification for certified rifle?

A. Yes.

Q. And there's also a certified pistol personal protection at home and personal protection outside the home?

A. Yes.

Q. Does that also relate to your professional work?

A. I don't do a whole lot of firearm safety. I've done some over the years. It's certainly an area that I would be happy to do work in.

Q. Are any of your certifications related to medical devices?

A. Not that I'm aware of.

Q. And then you have professional memberships and affiliations. You're a member of the American Society of Safety Engineers?

A. Yes.

Q. You're a member of the Human Factors and Ergonomics Society?

A. Yes. That needs to be updated.

Q. How so?

A. I'm the current program chair for the product technical group.

Q. You're also a member of the Illuminating Engineering Society?

A. Yes.

Q. What is that?

A. It's the Illuminating Engineering Society of North America. So it's professionals that are involved in the field of

lighting, artificial lighting, so whether it be workspace, workstation lighting, roadway lighting, et cetera.

Q. Okay. And then you have a number of publications and presentations here that are listed on your CV?

A. Yes.

Q. Do any of these publications or presentations deal specifically with medical devices?

A. I don't think that any of them deal specifically with medical devices. Some of them deal with over-the-counter medication labeling, some of them deal with prescription medication labeling.

Q. Okay. And then you have a section called technical reports?

A. Yes.

Q. Are these primarily technical reports from your work at IBM?

A. They're exclusively technical reports from my work at IBM.

Q. And I take it none of these technical report relate to medical devices?

A. There were no specific medical devices. I can't say that they don't relate to them because there's some -- some technical reports on, for example, the comparison of usability testing methodologies, which would be applicable to the design of medical devices, but it wasn't specific to medical devices.

Q. Okay. And then you have a list of published patents as well?

A. Yes.

Q. And none of the patents are for a medical device or components of a medical device?

A. I'll agree with the first one. The second one, I can't say that it's not because there are medical devices that use wireless technology, so I can't say that not.

Q. So you agree there's not a patent for a medical device?

A. None of them include a patent for a specific medical device.

Q. And you don't know whether or not one might be a component in a medical device?

A. I don't know if one might be related

or relevant to a medical device.
Q. You said you read the deposition of Rita Weaver?
A. Yes.
Q. Was there anything specific in that deposition that's germane to your warnings or labeling opinions?
A. I'm not recall anything specific offhand, and I don't think I specifically reference her in my report.
Q. Did you assess at all in your report the warnings or information provided to Ms. Weaver?
A. One more time.
Q. Did you assess at all in your report the warnings or information provided by Medtronic to Ms. Weaver?
A. I don't think I looked at any instructions or manuals that were provided to Ms. Weaver that was not provided to the Brackins or related to the pump, the infusion set or the reservoir.
Q. And you haven't provided any opinions in your report as to whether or not Rita Goidel

Weaver was adequately informed or warned regarding the Medtronic insulin pump reservoir or infusion set?
A. I do not address that in my report.
Q. And you don't address in your report any of the information that Ms. Weaver may have provided to the Brackins with respect to warnings and instructions for the insulin pump infusion set or reservoir?
A. I don't recall her providing the Brackins with any instruction or warning related to this issue or the issue that I'm addressing in my report.
Q. By that, you mean a temporary blocked vent?
A. Yes, or the necessity of ensuring the reservoir was on top of the insulin vial when removing it.
Q. You have a reference in the available materials the Urgent Medical Device Safety Notification from June 7, 2013.
A. You said available material?
Q. Yes.
A. All right. One more time, Urgent

Medical Device Safety Notification?
Q. Yes, it's referenced in the available materials.
A. Yes.
Q. Is that something you reviewed?
A. Yes.
Q. Did you make any analysis or assessment of the adequacy of that notification?
A. I did not. I'm not aware of the Brackins receiving the dear patient letter.
Q. If they didn't receive it, would it not be relevant to your analysis?
A. Yes and no.
Q. But in any case, you didn't assess it for adequacy in your report?
A. I didn't assess the dear patient letter for adequacy as the notification of the problem or issue to patients.
What I would have used it was -- what I would have used it for was again the background information of Medtronic's recognition of the issue and what was required to emphasize to the user and what they needed

to be informed about. So that would have been how I used that document.
Q. And you haven't done an assessment of Medtronic's CAPA investigation and response to the temporary blocked vent issue they discovered in 2012 to provide opinions in your report?
A. I don't have opinions in my report of Medtronic's CAPA response.
Q. And you're not providing any opinions about whether or not Medtronic complied with any specific FDA regulations with respect to the labeling or design of the insulin pump, reservoir or infusion set?
A. Yeah, I wasn't asked to or planning to provide any opinions regarding Medtronic's compliance to FDA regulations.
Q. As I understand it, your focus has been primarily on the industry standards that are not FDA related in terms of your analysis of human factors issues?
A. I would state that they're not FDA specific with regard to the issues I was addressing. I think that's the appropriate way

to state it.

Q. Are any of the guidances that you're relying upon, other than the 2000 and 2016 human factors FDA guidances, are any of them specifically related to medical devices?

A. Are you asking me if the specific references I cited in the report; is that what you're referring to?

Q. Let's do it a different way. Let's look at the references that are on page 25 of your report.

A. Sure, give me one second.

Okay.

Q. In coming to your opinion, are these the primary references you're utilizing in assessing whether or not Medtronic complied with human factors, principles and industry standards?

MR. HAVERTY: Objection. Asked and answered.

THE WITNESS: There are specific references that I'm using to support my opinions.

BY MR. MERRELL:

Q. Okay. And if you look at number four, that's the FDA 2000 guidance, and that does deal specifically with medical devices, correct?

A. That is a document titled guidance for industry and FDA reviewers on medical device use.

Q. And then you have, for example, a reference to number seven, Wagner 1992, risk taking and accident causation?

A. Yes.

Q. Outside of the reference number four, do any of the other ten references here deal specifically with medical devices?

A. No, they're not limited -- or they're not limited specifically to medical devices. They are references related to the design and development of any and all products and systems that are used by people.

So the warnings, references on how to design and development warnings, it's for the design and development of product warnings not specific or limited to a specific

subset of products. The human factors and safety guidelines are for product and development for all products and systems not limited to a specific subset or subtype of product or system.

Q. So references one through three and then four through 11 which you rely upon, those are assessing or addressing human factors design principles generally for all types of products?

A. Yes, I think it's one to three and then five through 11.

Q. Okay.

A. Because the four was the FDA that was specifically --

Q. Oh, sorry, I didn't mean to say four. So numbers one through three and then five through 11 deal with human factors principles for all products generally?

A. Products and systems, yes.

Q. Did you look for any other potential human factors guidances or industry standards that are specific to medical devices other than this number four and the 2016 guidance?

A. I did not.

Q. Did you look to see if there are any ANSI guidances with respect to medical devices specifically?

A. I'm not aware of any that were specific or relevant to what I was doing.

Q. Okay. And did you look at any specific industry standards, ISO standards or any kind of standard that were specific for risk assessment of a medical device in coming to your opinions?

A. I'm not familiar with an ISO standard specific for risk assessment of medical products. I am familiar with ISO standards for risk assessment in general, but not for medical products.

Q. You haven't listed any ISO standards on risk assessment, though?

A. I do not.

Q. Are there any that you rely upon in coming to your opinions here?

A. Well, yes and no. Again, as part of my general education, experience and training I'm well aware of both ANSI and ISO standards

for risk -- risk assessment, but I didn't feel the need to specifically reference them in the report.

Q. Are you citing to any particular ISO standard that Medtronic did not comply with in assessing the risk and hazard associated with the products at issue here?

A. I did not cite an ISO standard in my report.

Q. Have you told me today and what's contained in your report -- well, strike that.

What's contained in your report, does this contain the sum of your opinions in this case?

A. As I planned them as of this morning. So I think what I mean by that is, I think we talked about other areas that may not have been discussed specifically in the report. So I do hold whatever we talked about in our deposition today as opinions as well as what's in my report.

Q. Okay. But you haven't prepared any supplemental report for any additional opinions?

A. I have not.

Q. And have you provided all the underlying information for your opinions in your report either in your report or in your testimony today?

A. I tried to.

MR. MERRELL: Okay. I don't think I have any further questions.

Do you have any?

MR. HAVERTY: Yeah, I just have a couple just real quickly.

- - -

E X A M I N A T I O N

- - -

BY MR. HAVERTY:

Q. Dr. Vigilante, I don't want to belabor this too much, but we've been here going at this for a few hours now. But could you please give us the benefit -- could you tell us, please, a little bit about the field of human factors involves.

A. Sure. I do address what the field is in my report. But human factors is an applied science. And what I mean by that is that from

a basic science standpoint, human factors professionals, researchers, conduct research, things related to, for example, how people gather information through their senses, through whether it's sight, hearing, tactile, et cetera.

We look and study how people process information; that is, how they make decisions, how they store information into long-term memory, how information is transitioned into and out of short-term memory. We look at how people's experiences, their attitudes and beliefs, affect how they make decisions and how they perceive risks and so forth.

We also look at what we call physical ergonomics; that is, how the body moves, muscle strength, flexibility. I think I mentioned human gait earlier in the deposition. So these are all different topics that from a basic standpoint human factors professionals study. We take that information that we learn through basic science and we apply it to the design of products and systems.

So typically, human factors professionals -- for example, when I was with IBM, I would work with engineers, I'd work with designers, whether they're graphic designers, information designers, industrial designers, mechanical engineers, electrical engineers, et cetera, to design products.

So what we're trying to do is apply all of the stuff that we know about how people gather information, how they make decisions, the types of things that cause people to make mistakes or forget things.

We take that information and we apply to design. And the goal is to design systems that are easy to use, that are comfortable to use and that are safe. Essentially, what we want to do is design for human use, and human use includes all of our abilities as well as all of our limitations. So I think that's a general description of the field of human factors.

Q. And you were asked a number of questions about whether or not you had any involvement in these types of design defects --

design concepts from a human factors perspective as it relates to medical devices; do you recall that?

A. Yes.

Q. Is there anything that's unique about medical devices as to opposed to any other product that humans might use or interact with that would pose different human factor-type of analysis than, say, a computer keyboard or a cell phone or any other type of product?

A. The basic human factors principles and techniques apply regardless of the system or the product whether it's a medical device, a vehicle, workplace equipment, consumer product, et cetera.

Q. These are -- these are broadly applicable concepts and principles that you apply across all product lines and subproduct lines?

A. Yes, these are basic human factors principles and analysis techniques that are applicable to all system and product design.

Q. And did you apply those same types of techniques and that same type of methodology in

human factors that you apply to other types of products in this particular case?

A. I did.

MR. HAVERTY: Okay. That's all I have. Thanks.

- - -

E X A M I N A T I O N

- - -

BY MR. MERRELL:

Q. Do you have any experience in academics teaching human factors principles?

A. Other than subbing in for professors that were on vacation, I don't think so. I was not an associate or adjunct professor like that. At undergraduate, I taught research methods labs, and I think that's probably the extent of my teaching experience.

Q. Okay. About how many times do you think you subbed in for a professor to teach?

A. I think it's probably a handful.

Q. Have you ever -- do you have any experience conducting failure modes and effects analysis for a device, a product?

A. I do. I'm sorry?

Q. You do?

A. Yes.

Q. How many times have you put something like that together?

A. I don't know. I can't give you a number. I can tell you my experience at IBM is that I would be responsible for the total FMEA that was conducted on the products. I would be responsible of inputting into the FMEA that was done.

Q. And I take it, though, you've never done an F-M-E-A for a medical device?

A. Outside of the Dennert and Brackin, I have not.

Q. Have you actually done an F-M-E-A in this case?

A. Well, part of the task analysis gets into the failure effect modes analysis. So, for example, for the failure mode and effects analysis you're looking at different aspects of the design where an error or problem in a specific component can result in what type of -- what type of hazards it can result in and how it can -- how it could come about. So a

lot of task analysis information related to types of errors and hazards that are a result of those errors are typically fed back into a larger FMEA.

Q. And in this case, you've looked at a specific issue with respect to the F-M-E-A and that's the TBV?

I'll just say it again.

A. Oh, I'm sorry.

Q. In this case, you looked at the F-M-E-A or the D-F-M-E-A analysis you've done in this case is specific to temporary blocked vent?

A. Yes, my analysis was focused on the temporary blocked vent event.

Q. Did you review the entire D-F-M-E-A for the products at issue here?

A. I did not.

Q. Did you do a full D-F-M-E-A analysis of all potential risks and hazards --

A. I did not.

Q. -- all those products?

A. Sorry. I did not.

Q. And you've never conducted that sort

WILLIAM J. VIGILANTE, JR.

of analysis for a medical device?

A. A total?

Q. Correct.

A. I have not.

Q. Your only experience with a D-F-M-E-A in litigation in this case and then the Dennert case?

A. Well, no. Again, through my work with IBM, it was part of my responsibilities to feed into the overall failure modes, effects analysis and the other parts of the hazard analysis that were done.

Q. But you've never done a D-F-M-E-A for a medical device or any sort of analysis like that outside of your work in litigation of the Dennert case and the Brackin case?

A. Not that I'm aware of.

Q. You mentioned that a medical device isn't really any -- there's nothing unique about a medical device compared to other potential products for assessing from a human factors perspective; is that about right?

A. Correct.

Q. Wouldn't you agree that there is

WILLIAM J. VIGILANTE, JR.

something unique about a medical device in that many of them are implanted into the human body and many of them such as this one are actually infusing medication into the human body?

A. I agree that medical devices can -- some medical devices are implanted in the human body and some of them infuse drugs into the human body. But from a design perspective, there's got to be a user involved at some point, and human factors is studying that user interaction, so the same principles, basic principles, analysis apply.

MR. HAVERTY: Okay. No further questions.

- - -

E X A M I N A T I O N

- - -

BY MR. HAVERTY:

Q. Just real quickly.

Dr. Vigilante, you were asked questions about failure modes and effect analysis. Again, are the concepts of how to -- how to do a failure mode and effects analysis general concepts that are applicable across all

WILLIAM J. VIGILANTE, JR.

types of products?

A. Yes.

Q. And it's not -- there's nothing specific or unique about a failure modes and effects analysis as it applies to a medical device as opposed to an automobile or any other type of product, right?

A. No.

MR. HAVERTY: Okay.

- - -

E X A M I N A T I O N

- - -

BY MR. MERRELL:

Q. Do you know what ISO standards apply to a failure modes and effects analysis for a medical device?

A. Not offhand.

Q. Are you aware of any unique ISO standards with respect to the failure modes and effects analysis for a medical device?

A. Not offhand.

MR. MERRELL: Okay. No further questions.

MR. HAVERTY: That's all. We're

WILLIAM J. VIGILANTE, JR.

done.

THE VIDEOGRAPHER: This ends DVD number four. The video time is now 2:49. This ends the deposition today. We are now going off record.

THE COURT REPORTER: Can you confirm for the record that you want a rough draft and a regular final.

MR. HAVERTY: Yes, please.

THE COURT REPORTER: And you want a rough draft and immediate final.

MR. MERRELL: Yes, thanks.

- - -

(Whereupon, the deposition was concluded at 2:47 p.m.)

- - -

WILLIAM J. VIGILANTE, JR.

I N D E X

\- - -

E X H I B I T S

WILLIAM J. VIGILANTE, JR.

CERTIFICATE

I HEREBY CERTIFY that the proceedings, evidence and objections are contained fully and accurately in the stenographic notes taken by me upon the deposition of WILLIAM J. VIGILANTE, JR. taken on September 14, 2018 and that this is a true and correct transcript of same.

Dated: September 14, 2018

____

Jennifer Miller, RPR and
Notary Public

WILLIAM J. VIGILANTE, JR.

NAME OF CASE:

NAME OF WITNESS:

Reason Codes:

1. To clarify the record.
2. To conform to the facts.
3. To correct transcription errors.

Page ______ Line ______ Reason ______
From _____________________ to _____________________
Page ______ Line ______ Reason ______
From _____________________ to _____________________
Page ______ Line ______ Reason ______
From _____________________ to _____________________
Page ______ Line ______ Reason ______
From _____________________ to _____________________
Page ______ Line ______ Reason ______
From _____________________ to _____________________
Page ______ Line ______ Reason ______
From _____________________ to _____________________
Page ______ Line ______ Reason ______
From _____________________ to _____________________
Page ______ Line ______ Reason ______
From _____________________ to _____________________

____

WILLIAM J. VIGILANTE, JR.

I have inspected and read my deposition as captioned above and have listed all changes and corrections above, along with my reasons therefore.

DATE:____________________

SIGNATURE OF DEPONENT: ____________________

I have read the foregoing transcript of my deposition and it is true, correct and complete, to the best of my knowledge, recollection and belief, except for the corrections noted hereon and/or list of corrections, if any, attached on a separate sheet herewith.

____

WILLIAM J. VIGILANTE, JR.

Subscribed and sworn to before me this ____ day of ________________, 2018.

____

Notary Public

N